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(54) **INSTRUMENTS AND METHODS OF SOFT TISSUE FIXATION**

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CPC .. ***A61B 17/0401*** (2013.01); *A61B 2017/0409* (2013.01); *A61B 2017/0464* (2013.01)

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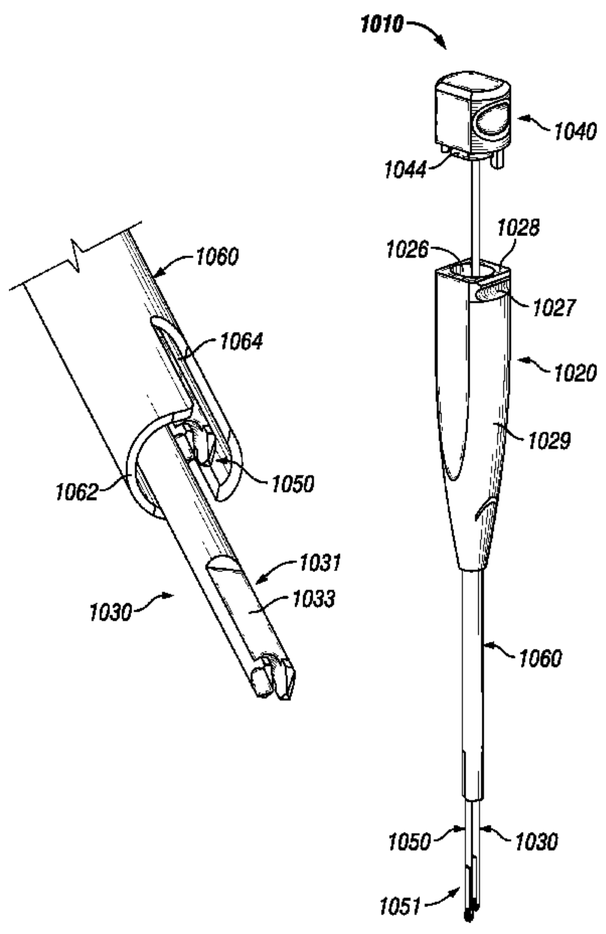
(57) **ABSTRACT**

An inserter assembly for inserting anchors into bone includes a handle having a handle body. A first inserter is disposed within the handle body and is fixedly connected thereto. The first inserter has an insertion end configured to retain a first anchor for insertion thereof into bone. A second inserter is slidably disposed within the handle body and has an insertion end configured to retain a second anchor for insertion thereof into bone. A sleeve is slidably disposed within the handle body and is releasably connected to the second inserter.

20 Claims, 31 Drawing Sheets



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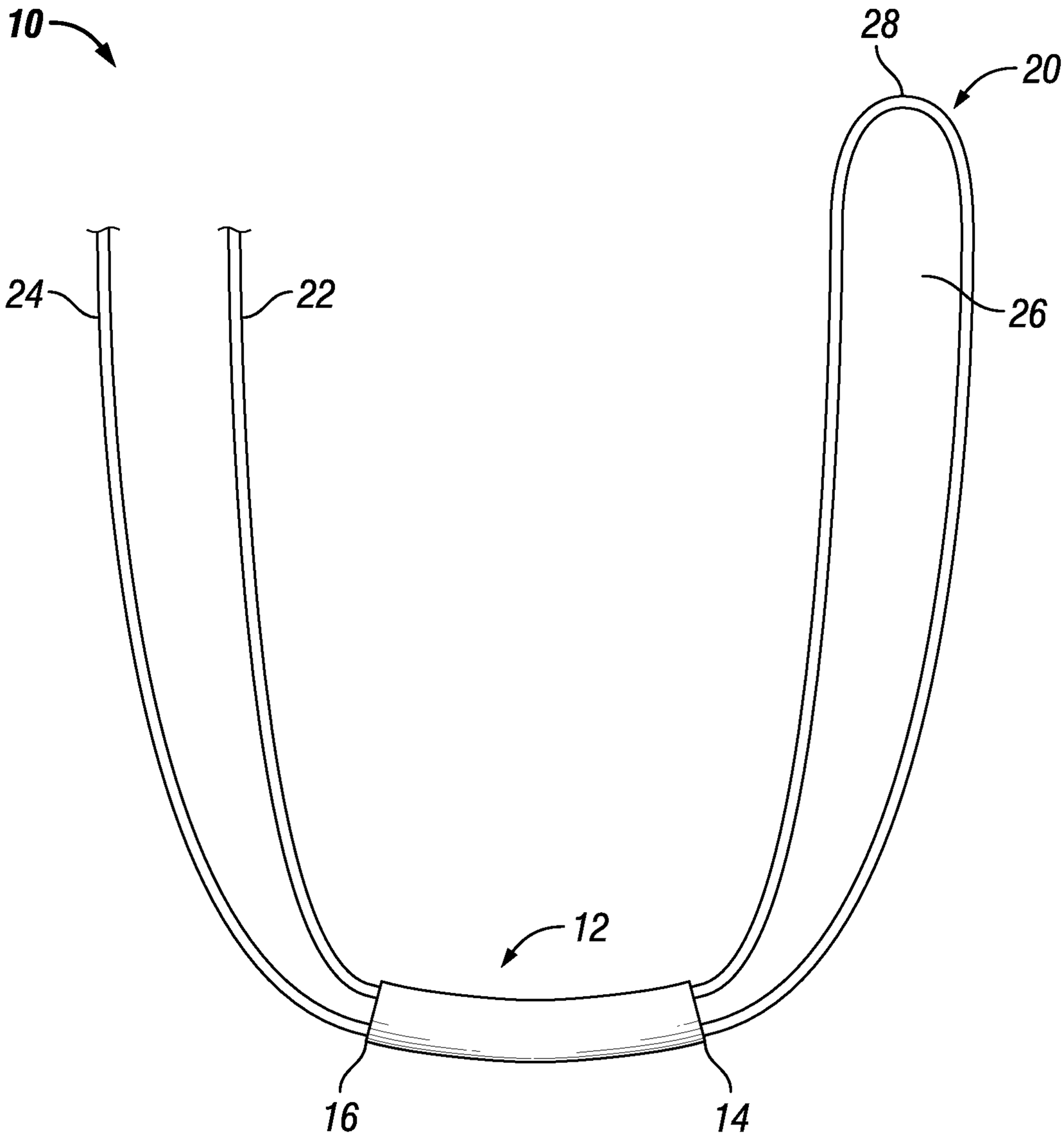


FIG. 1A

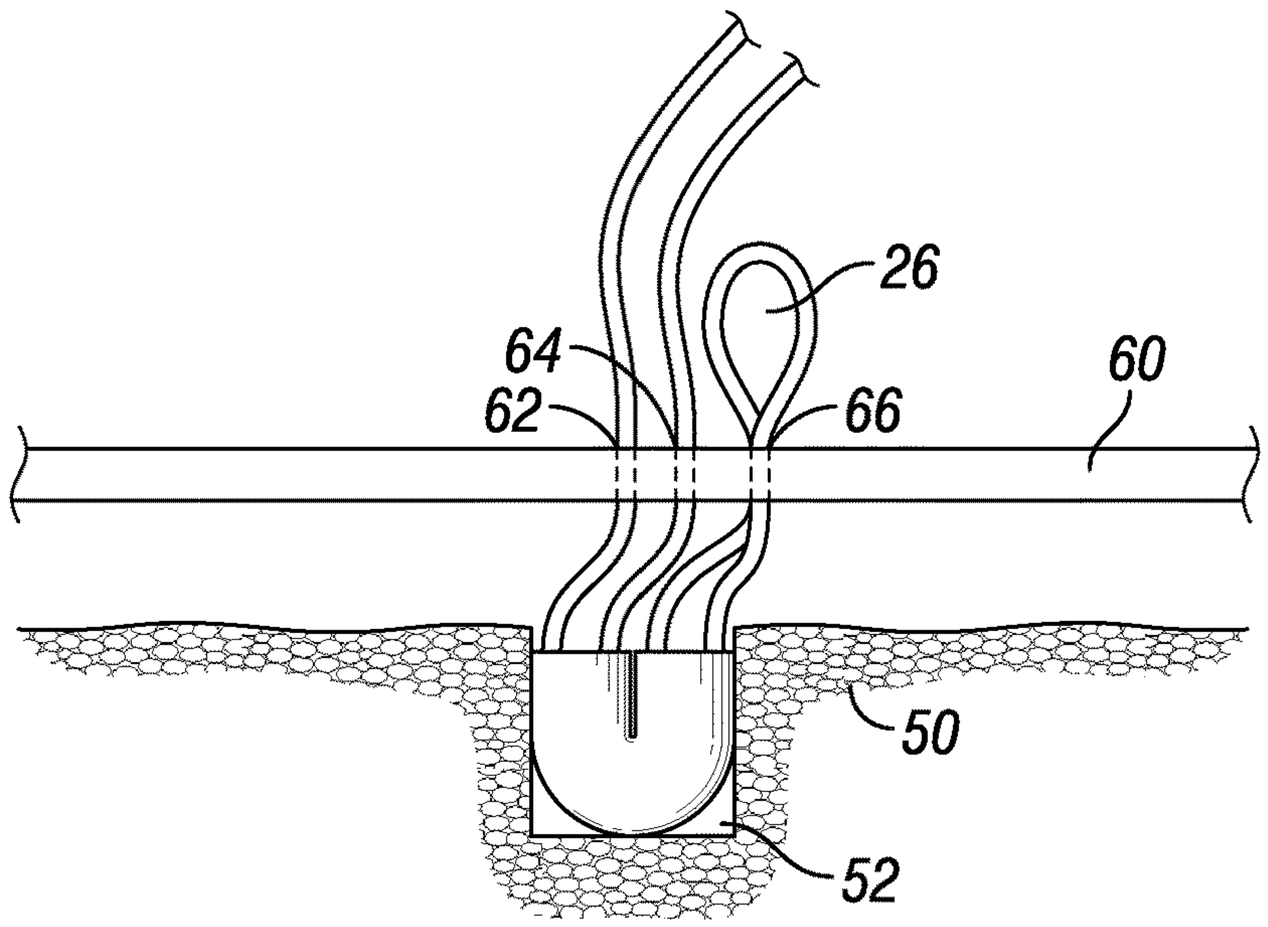


FIG. 1B

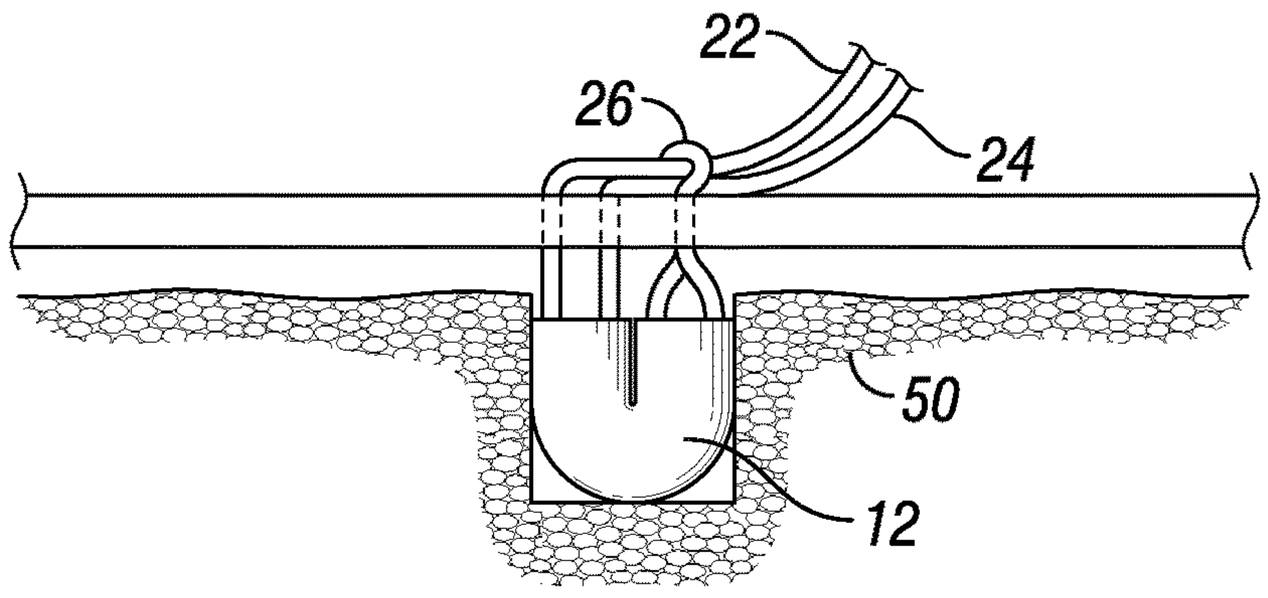


FIG. 1C

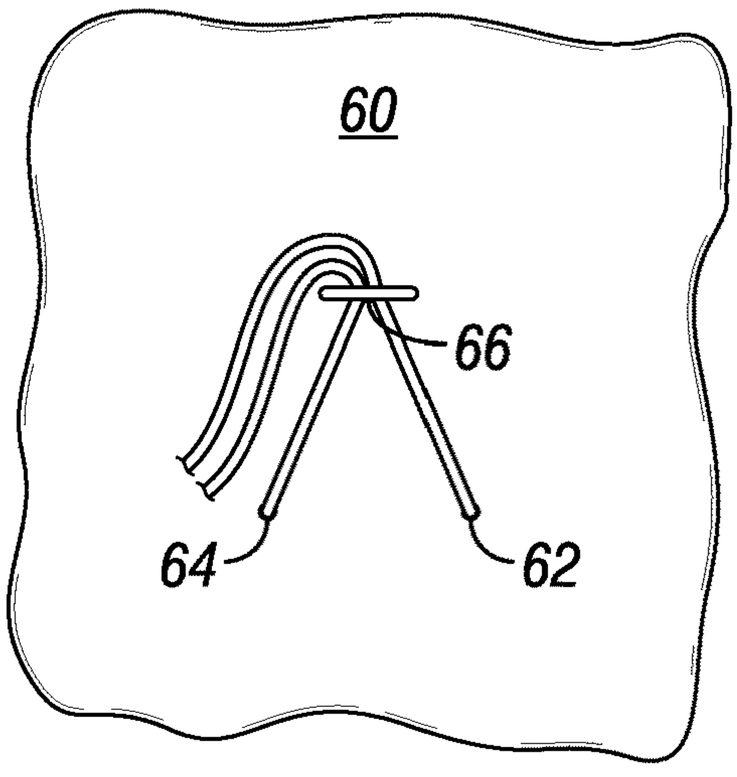


FIG. 1D

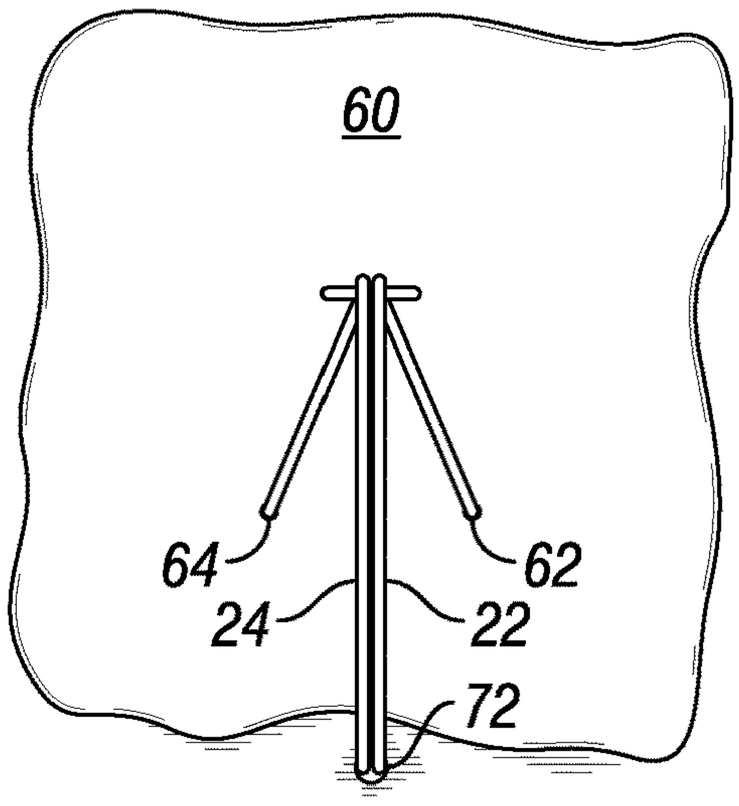


FIG. 1E

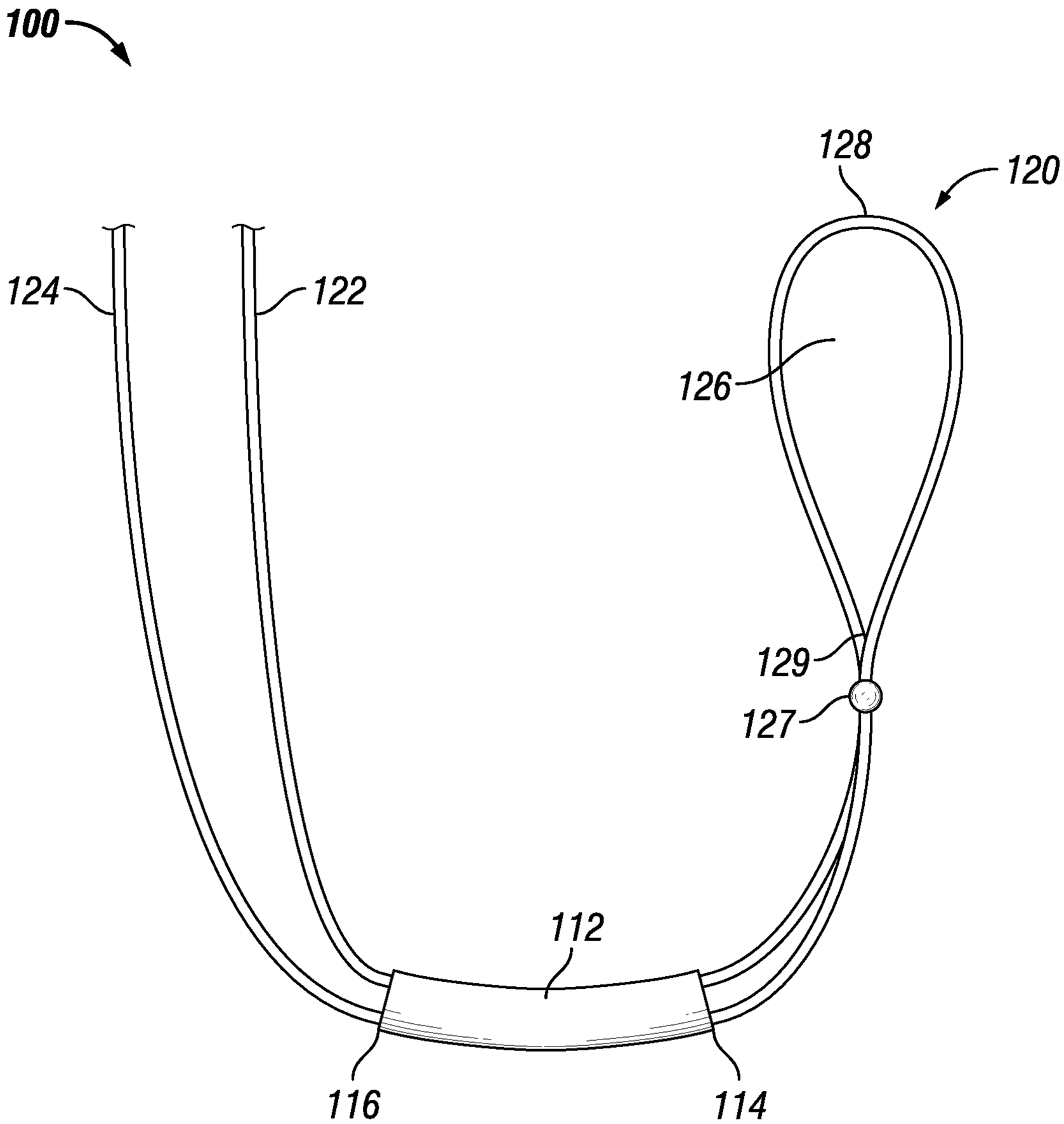
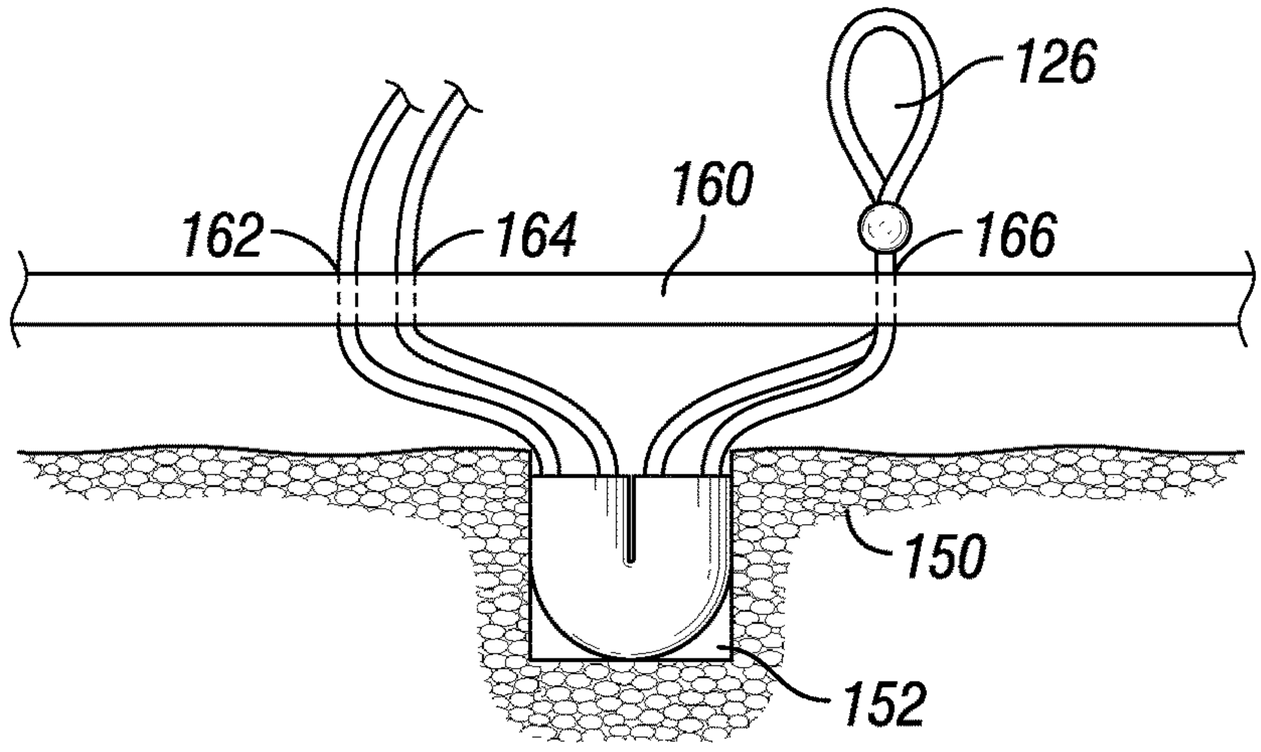


FIG. 2A



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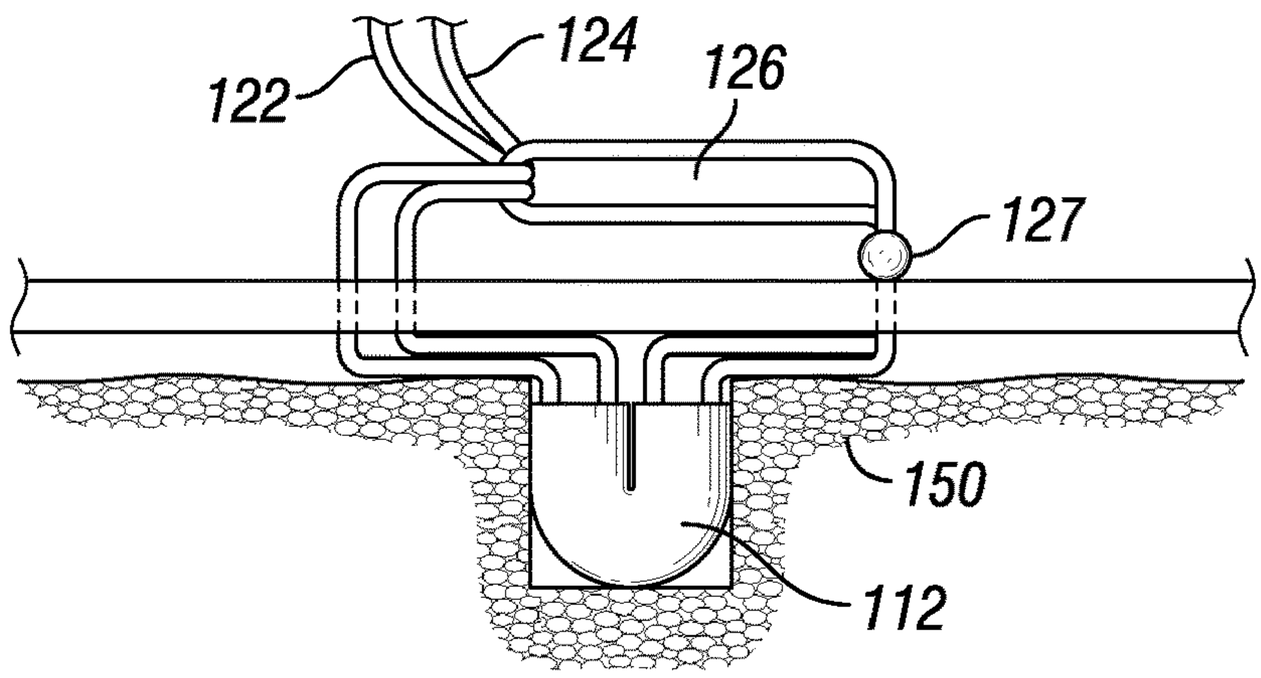


FIG. 2C

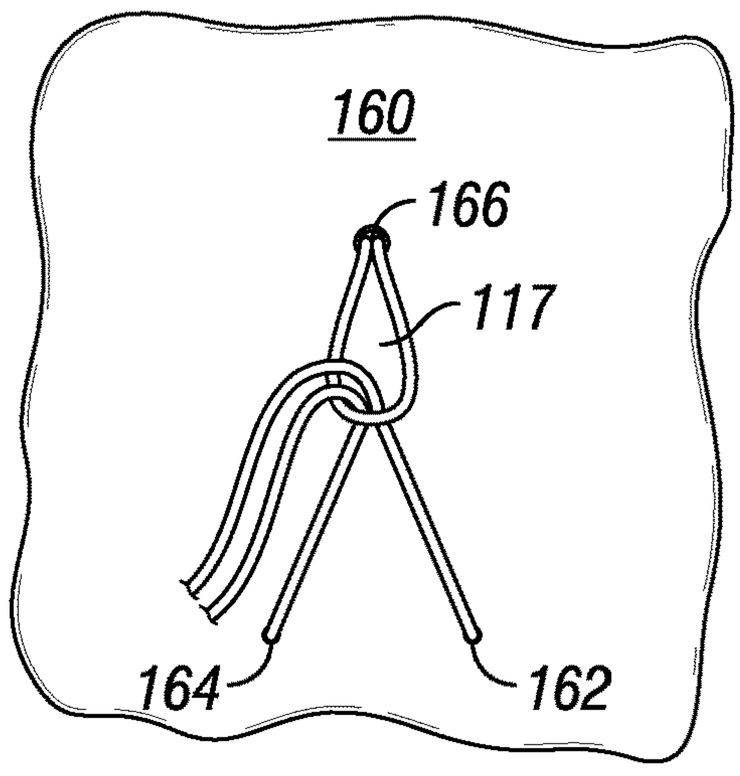


FIG. 2D

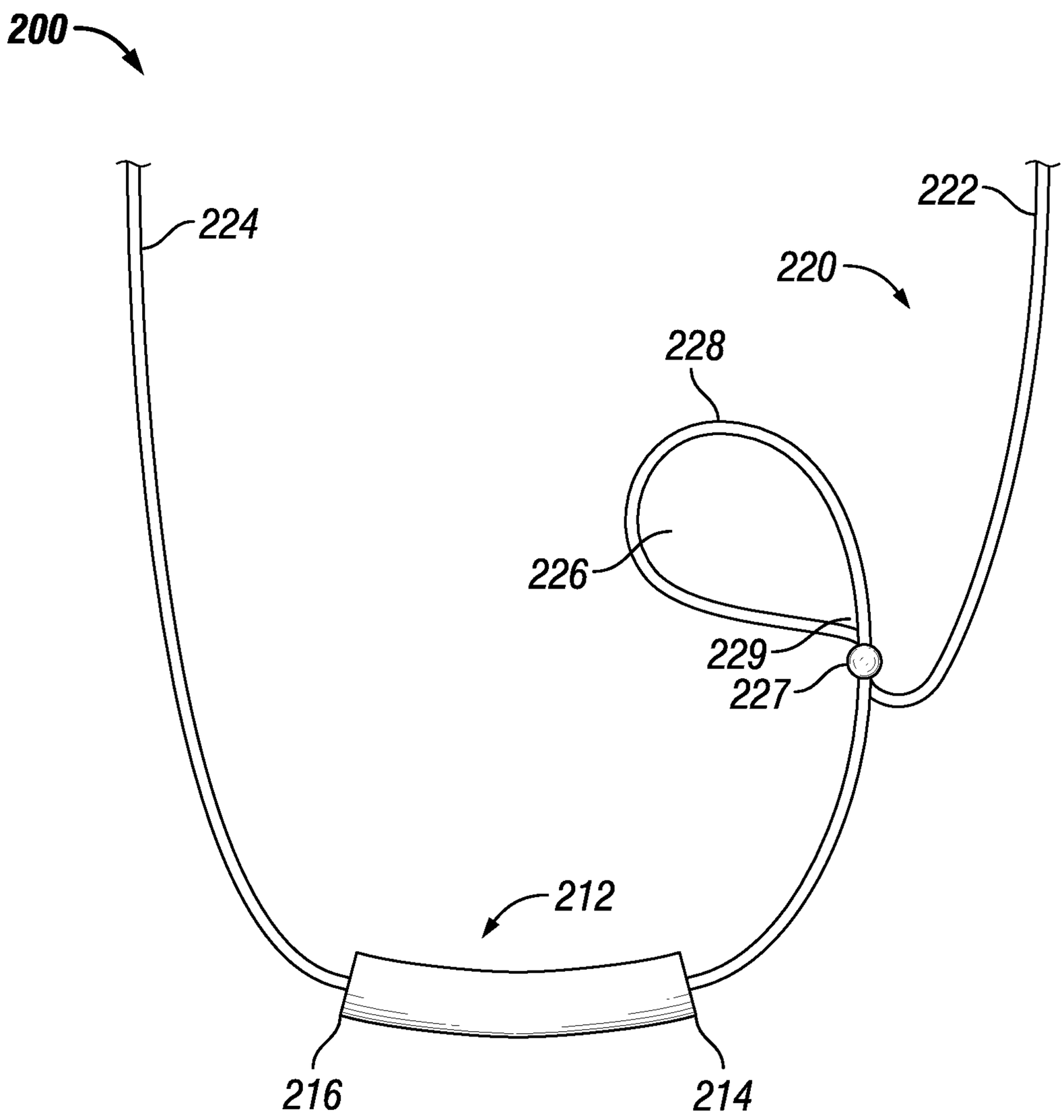
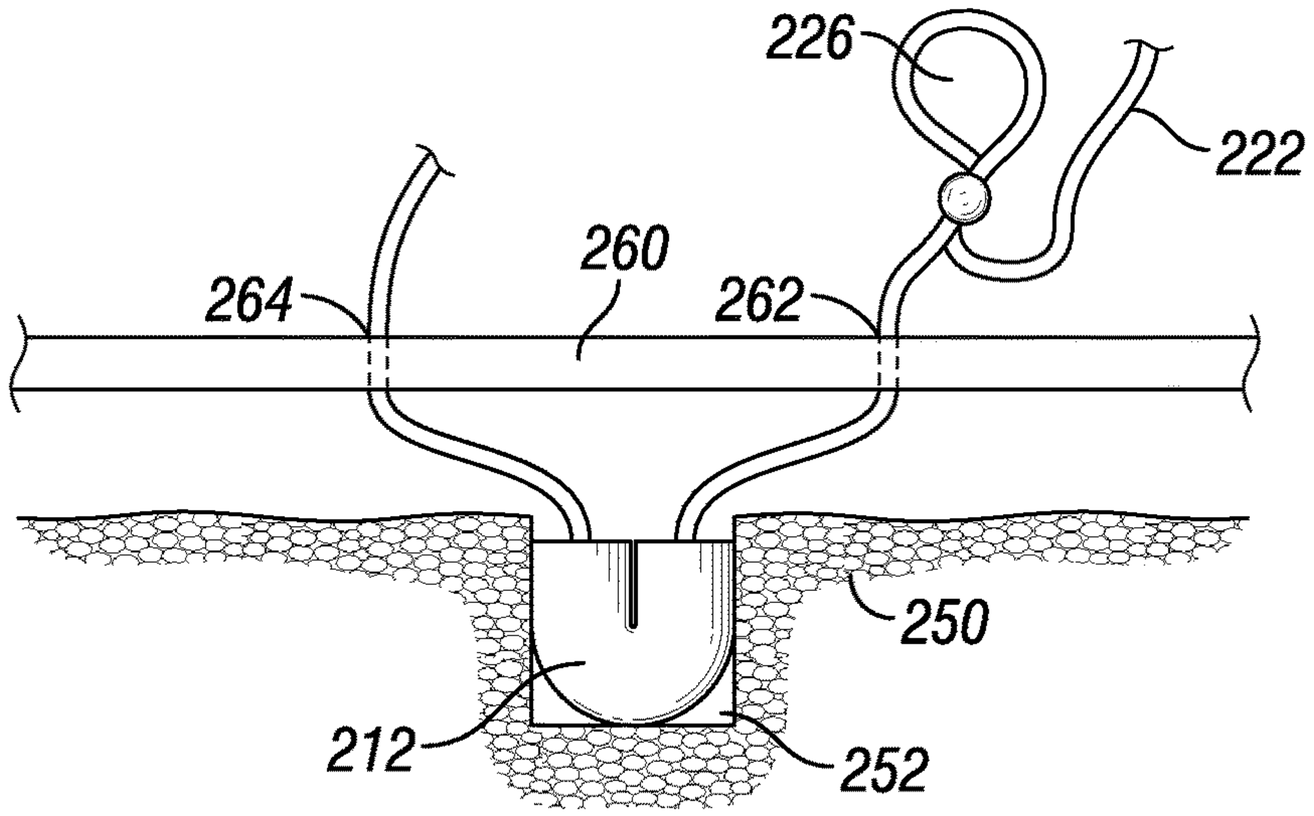


FIG. 3A



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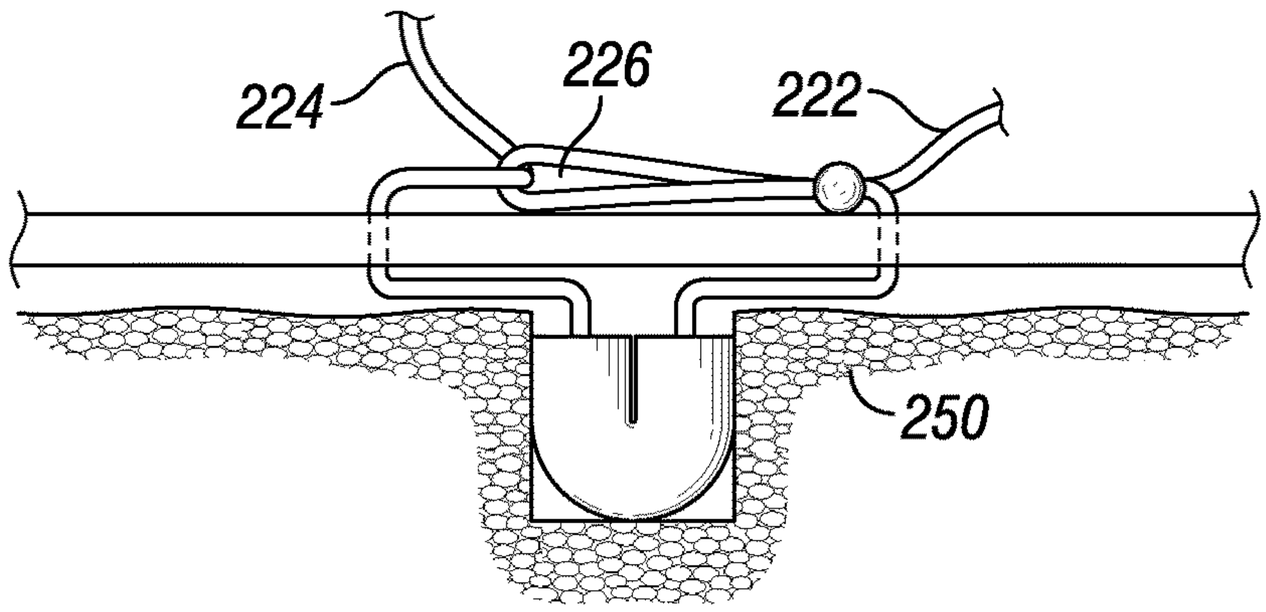

FIG. 3C

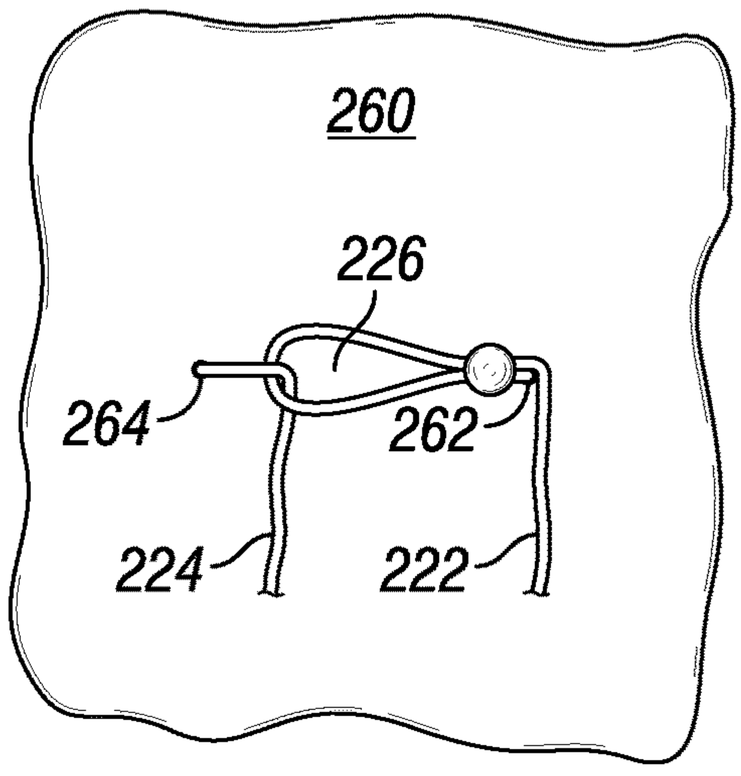

FIG. 3D

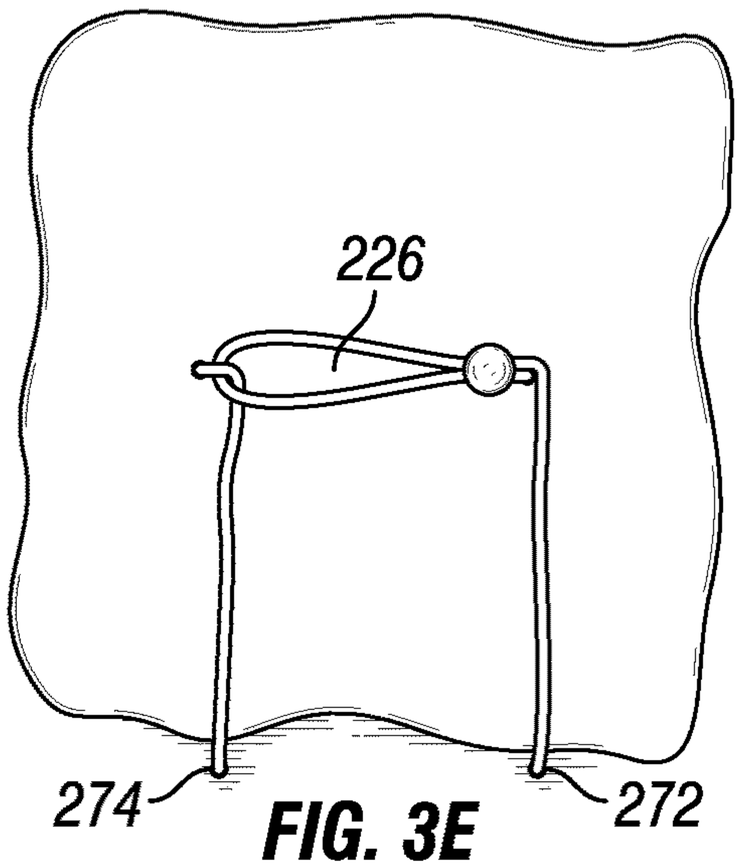

FIG. 3E

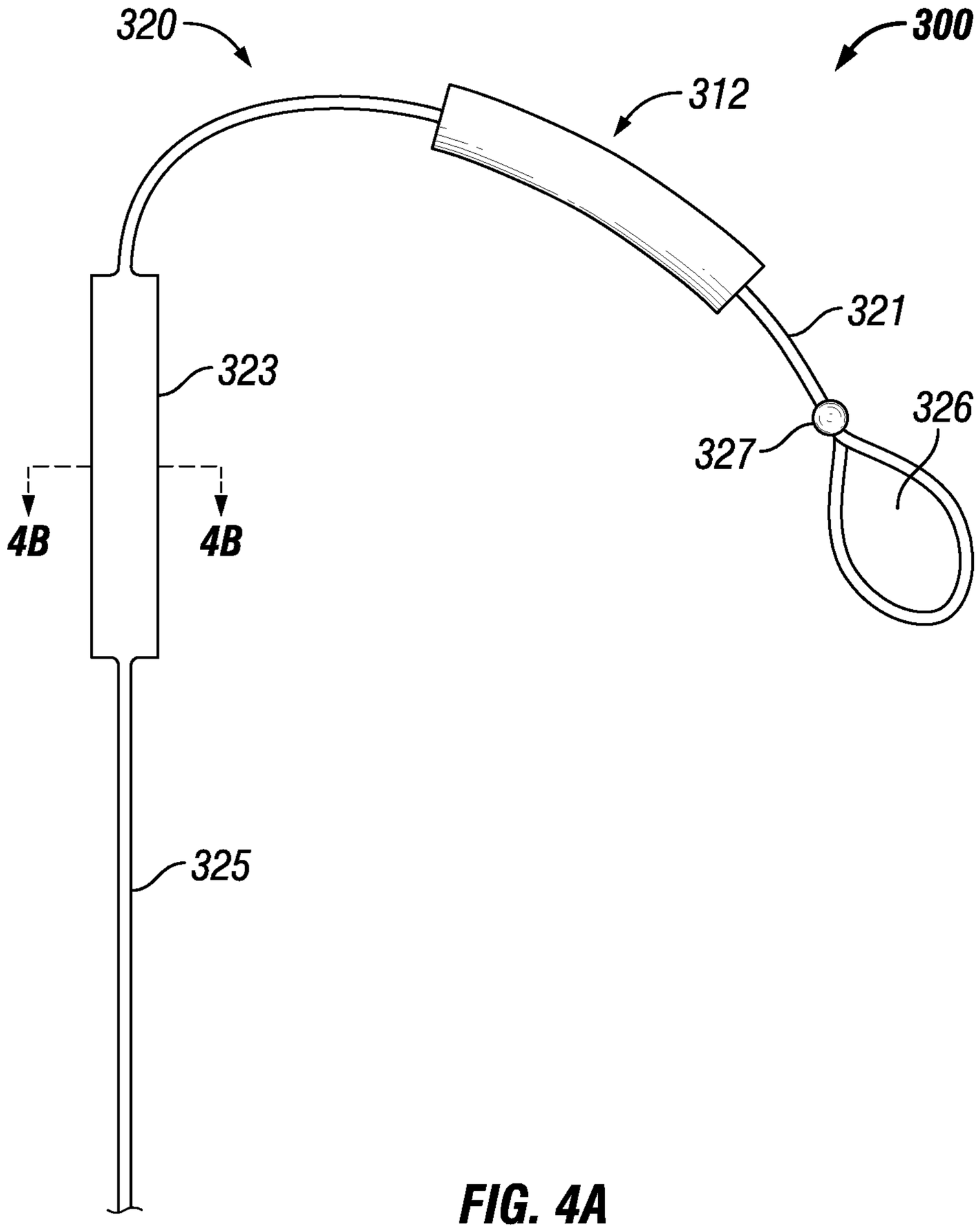

FIG. 4A

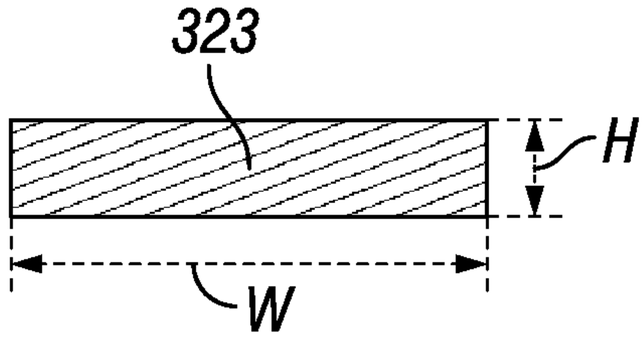

FIG. 4B

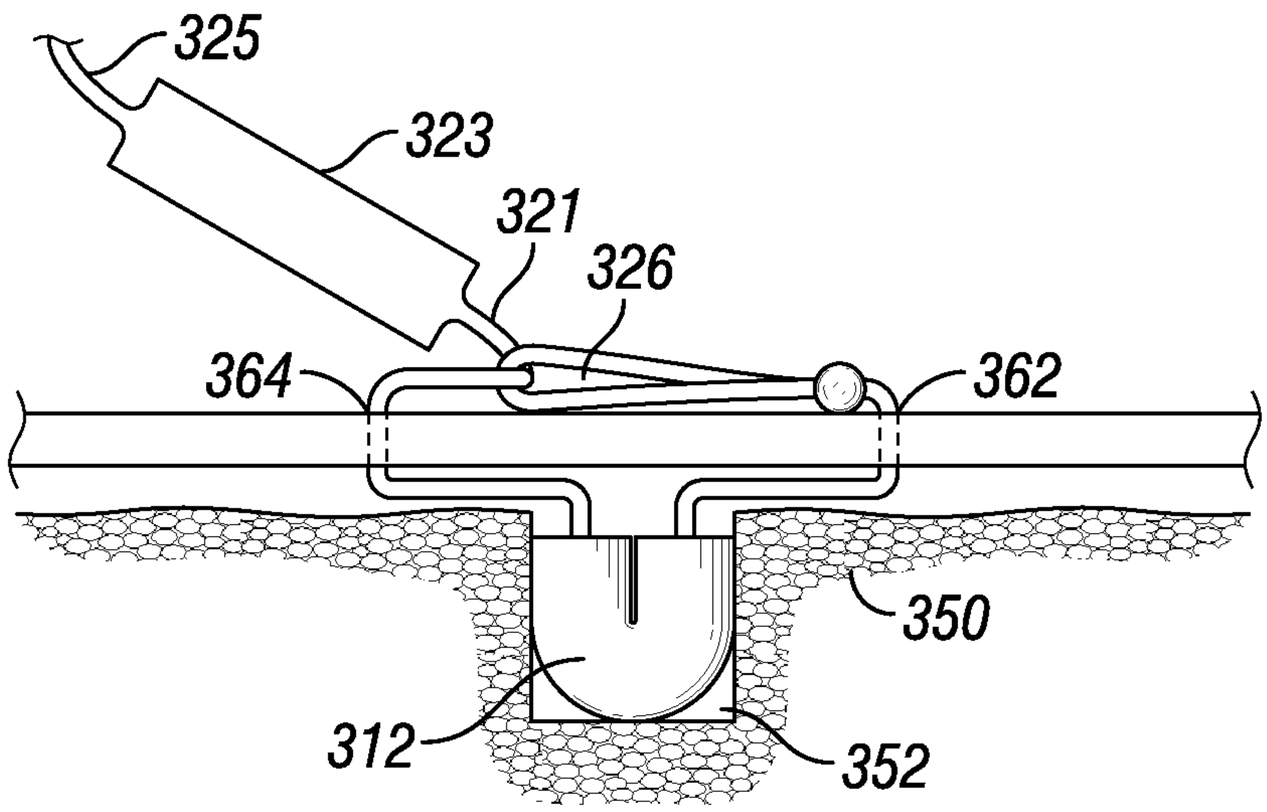

FIG. 4C

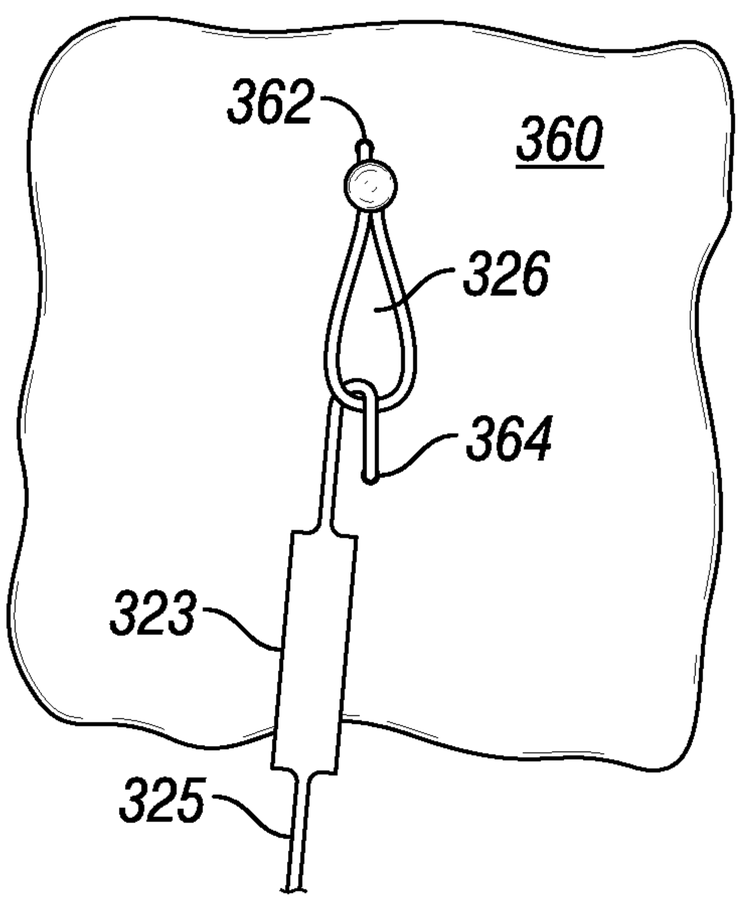

FIG. 4D

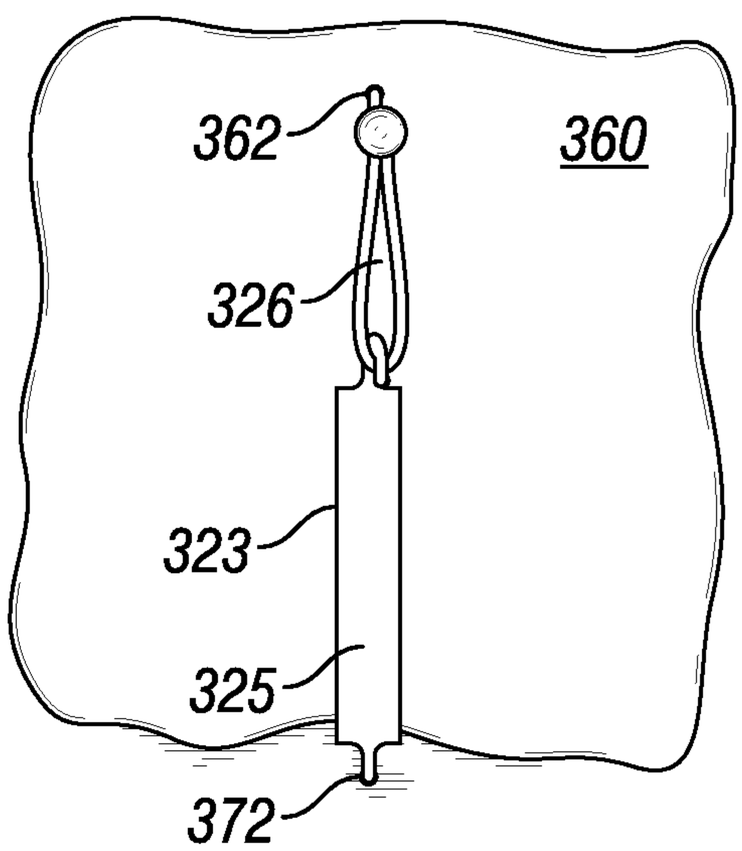

FIG. 4E

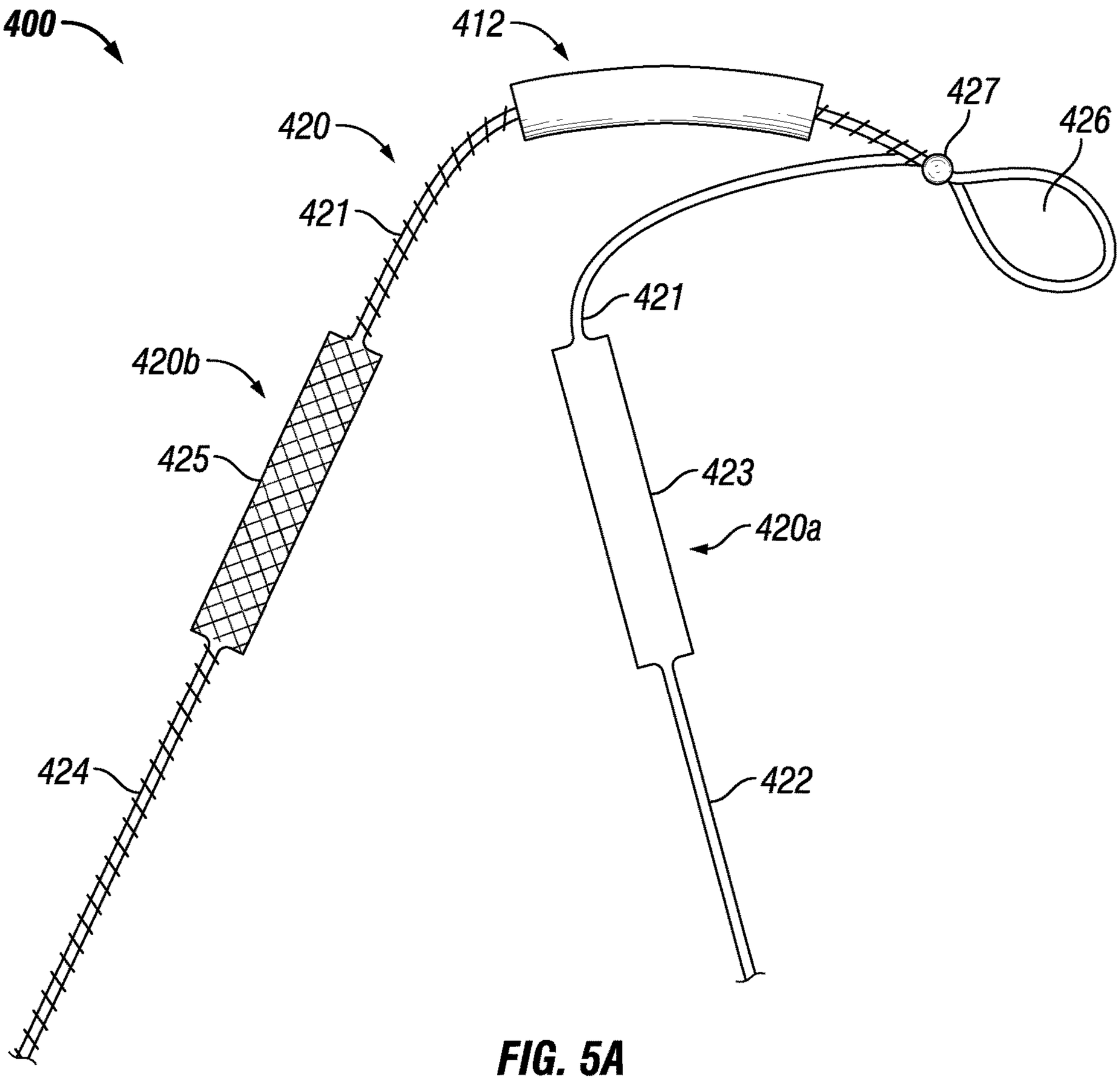

FIG. 5A

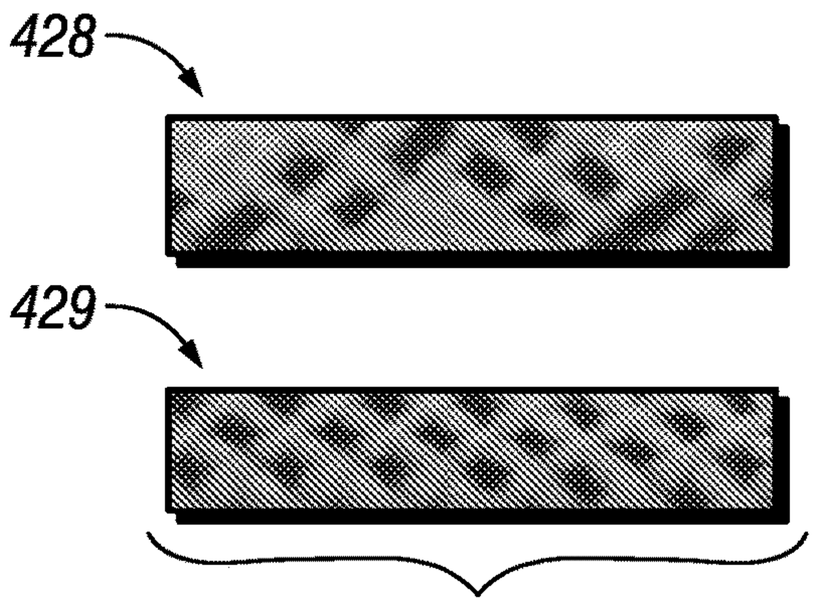

FIG. 5B

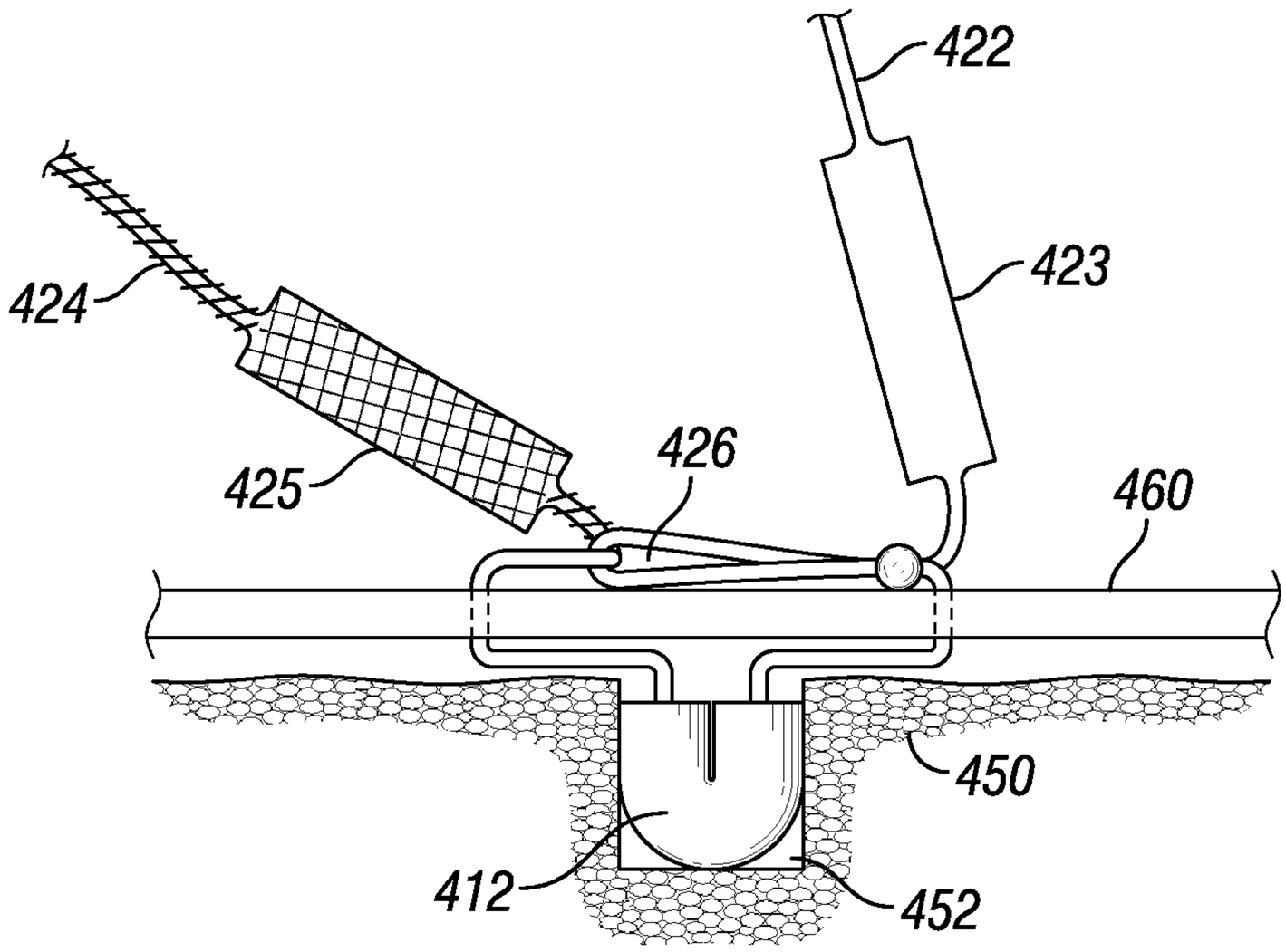

FIG. 5C

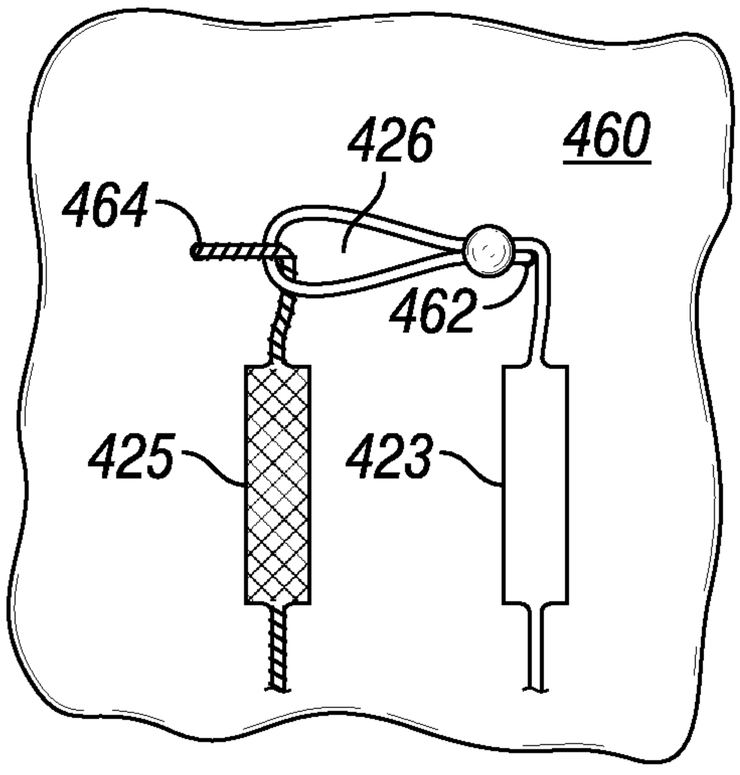

FIG. 5D

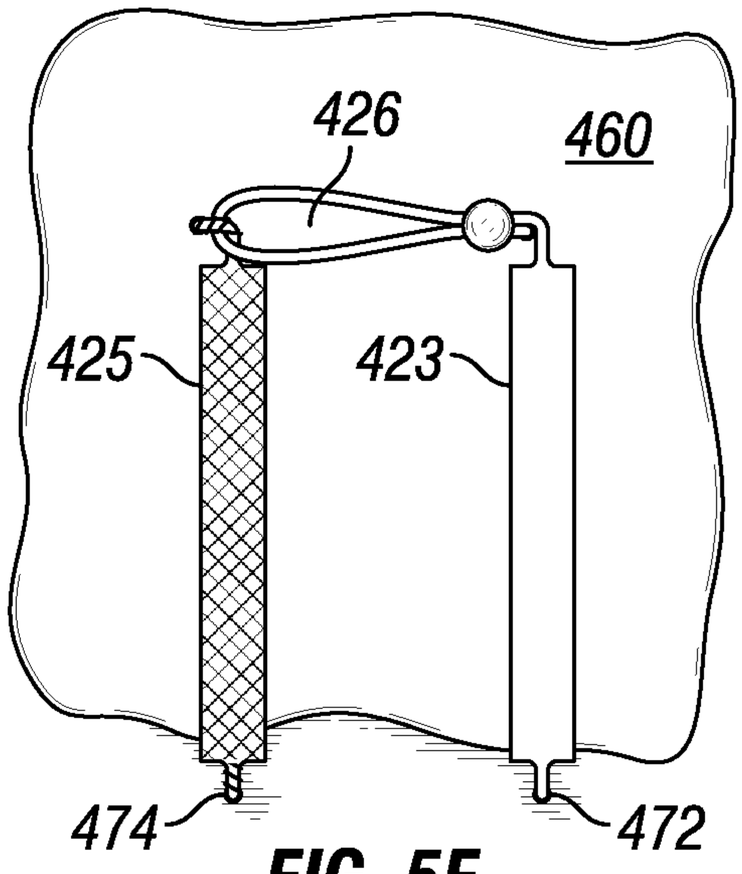

FIG. 5E

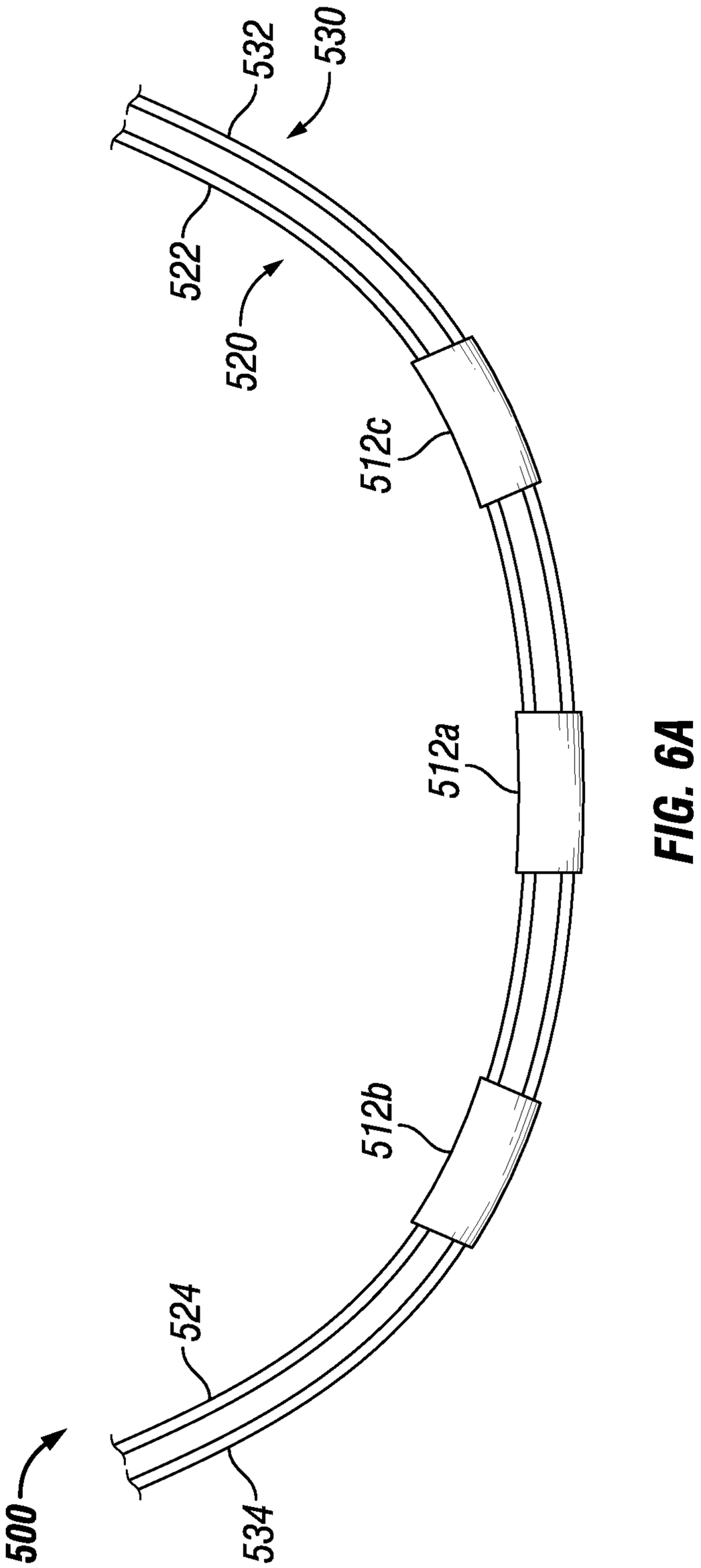

FIG. 6A

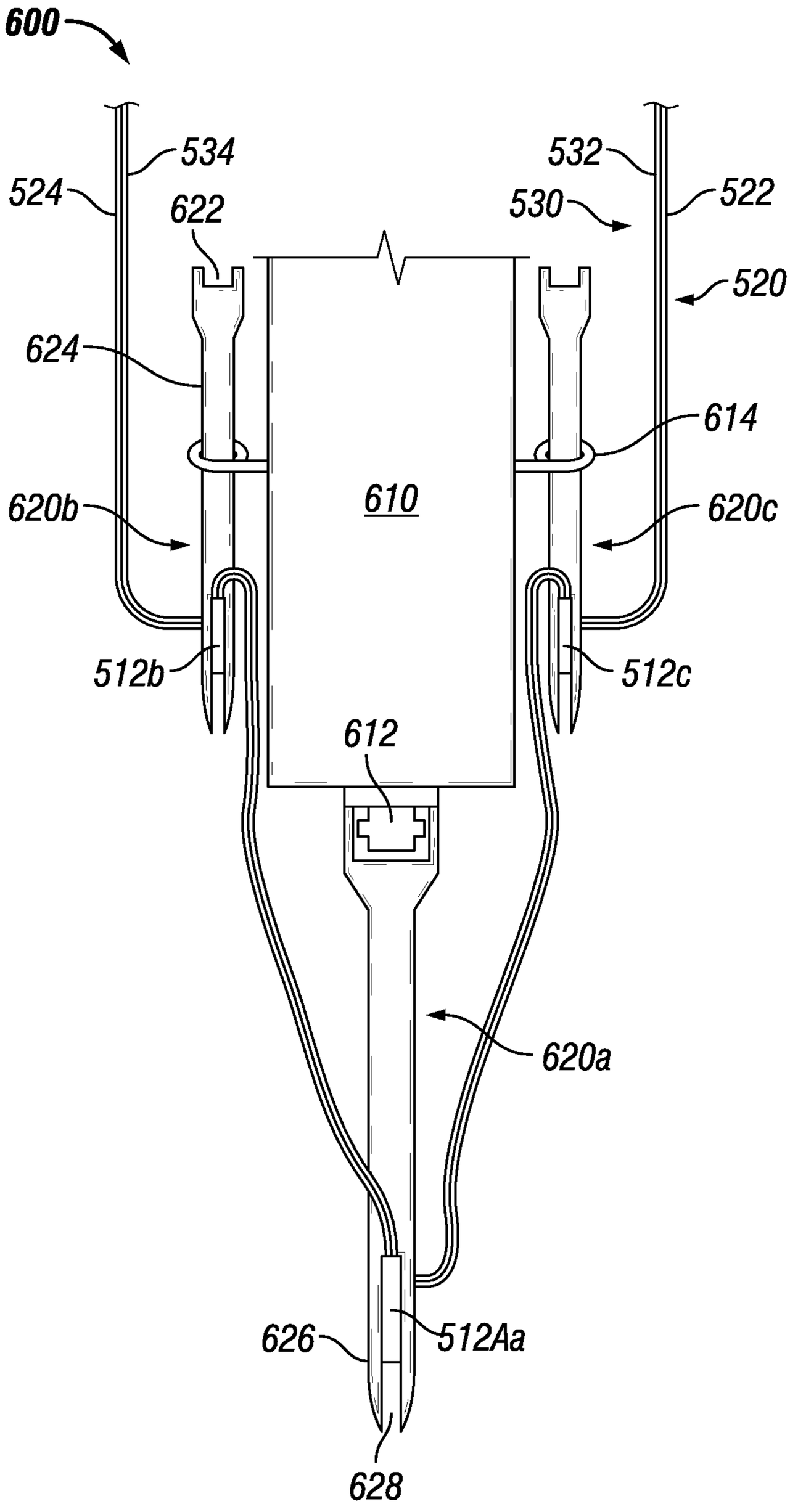
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FIG. 6B

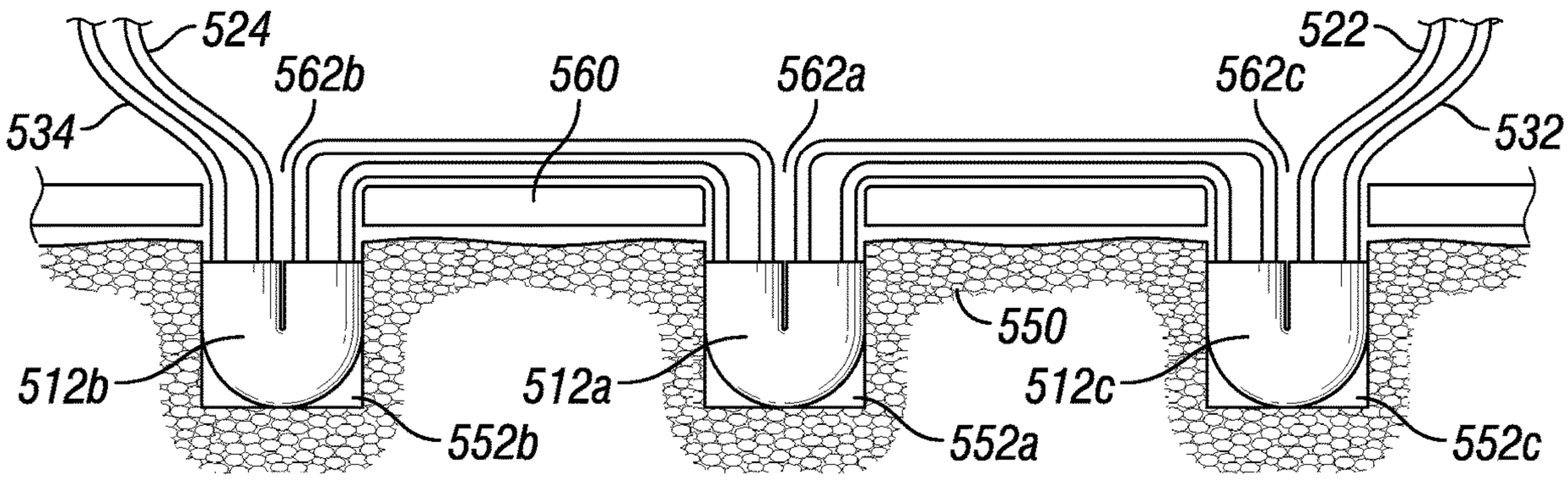

FIG. 6C

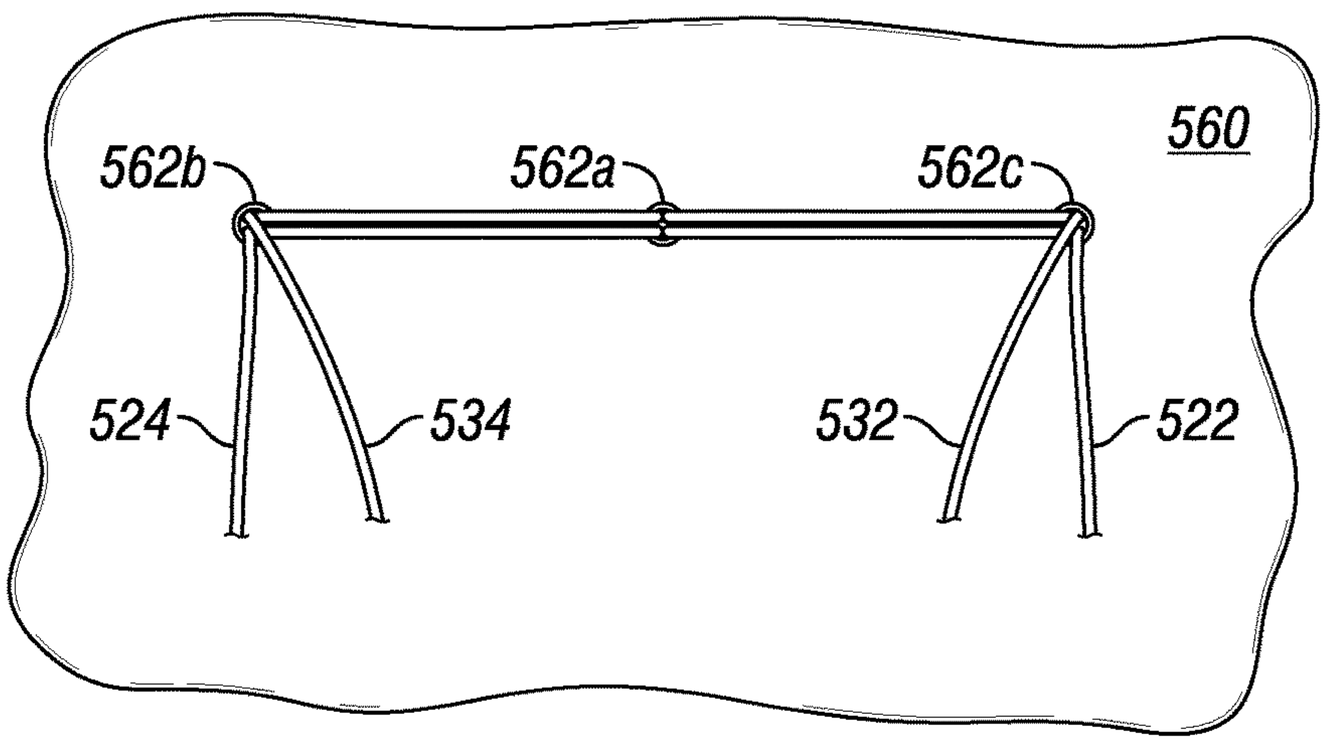

FIG. 6D

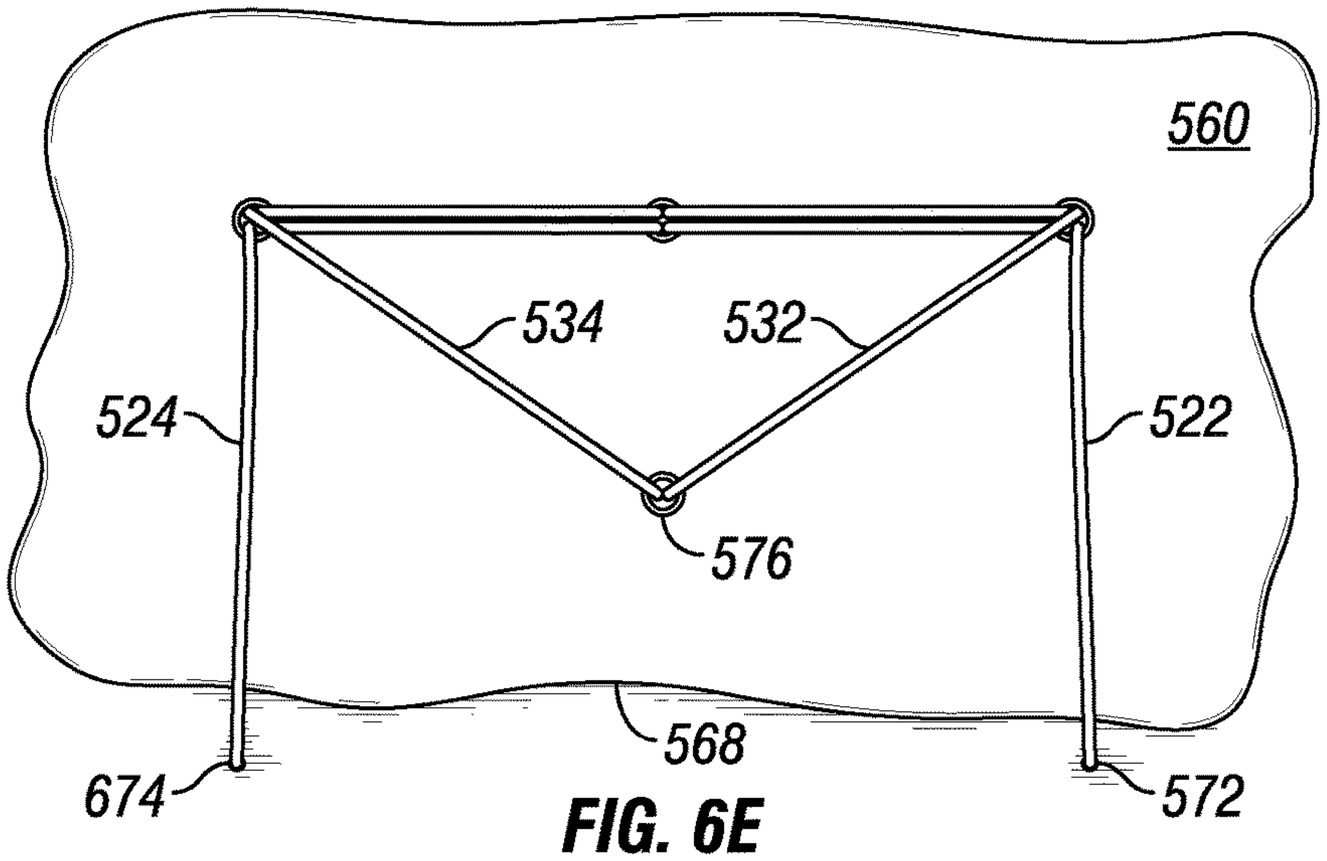

FIG. 6E

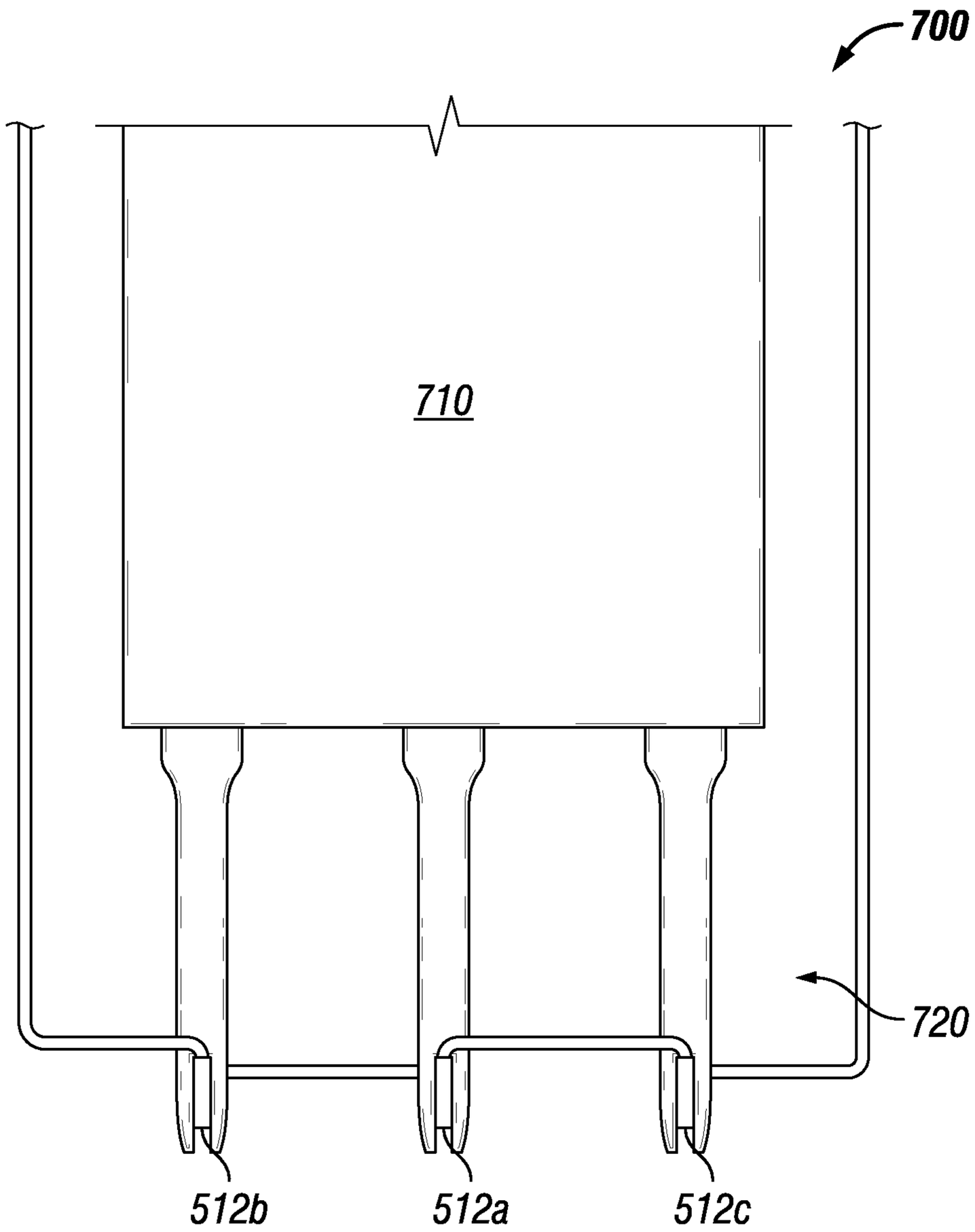

FIG. 7

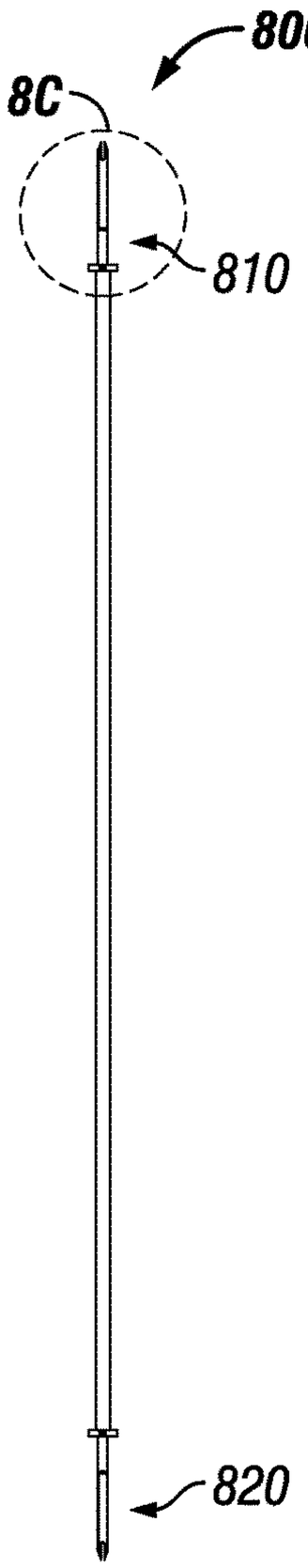

FIG. 8A

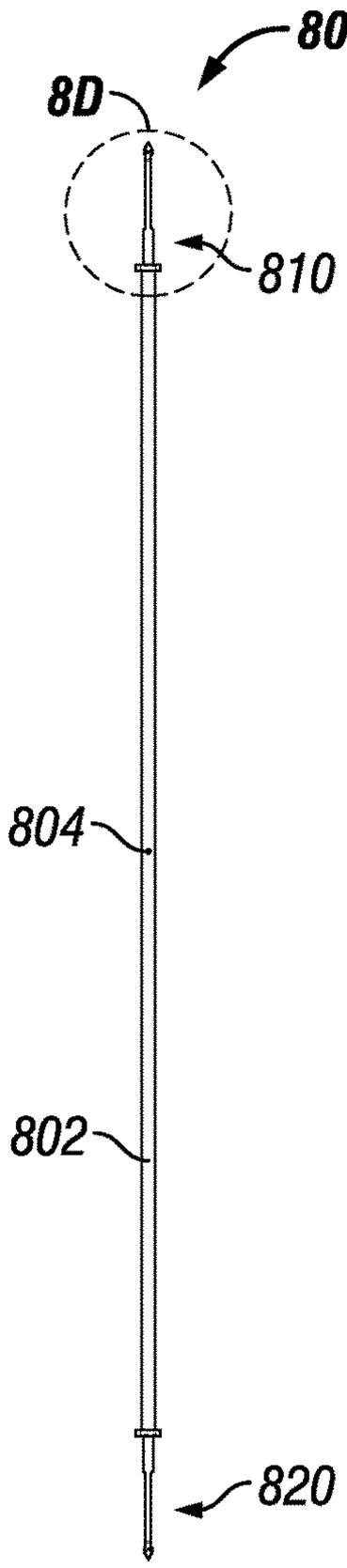

FIG. 8B

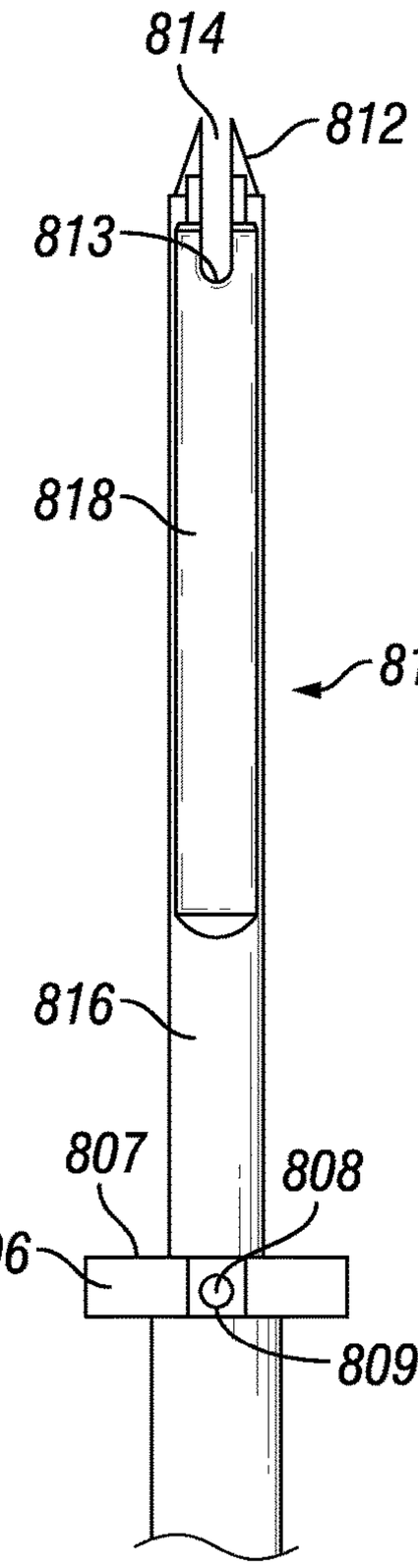

FIG. 8C

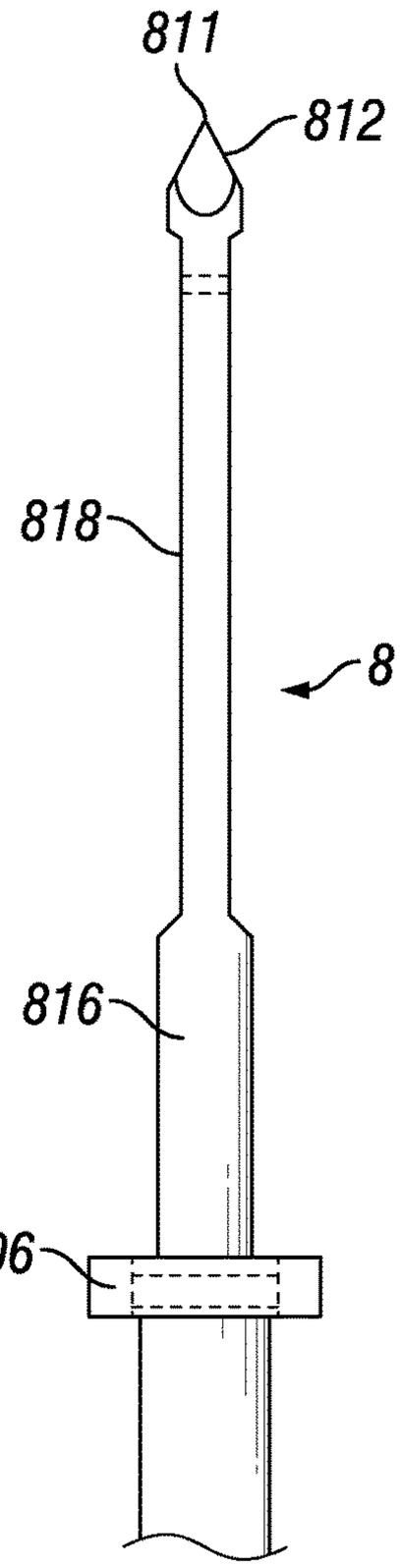

FIG. 8D

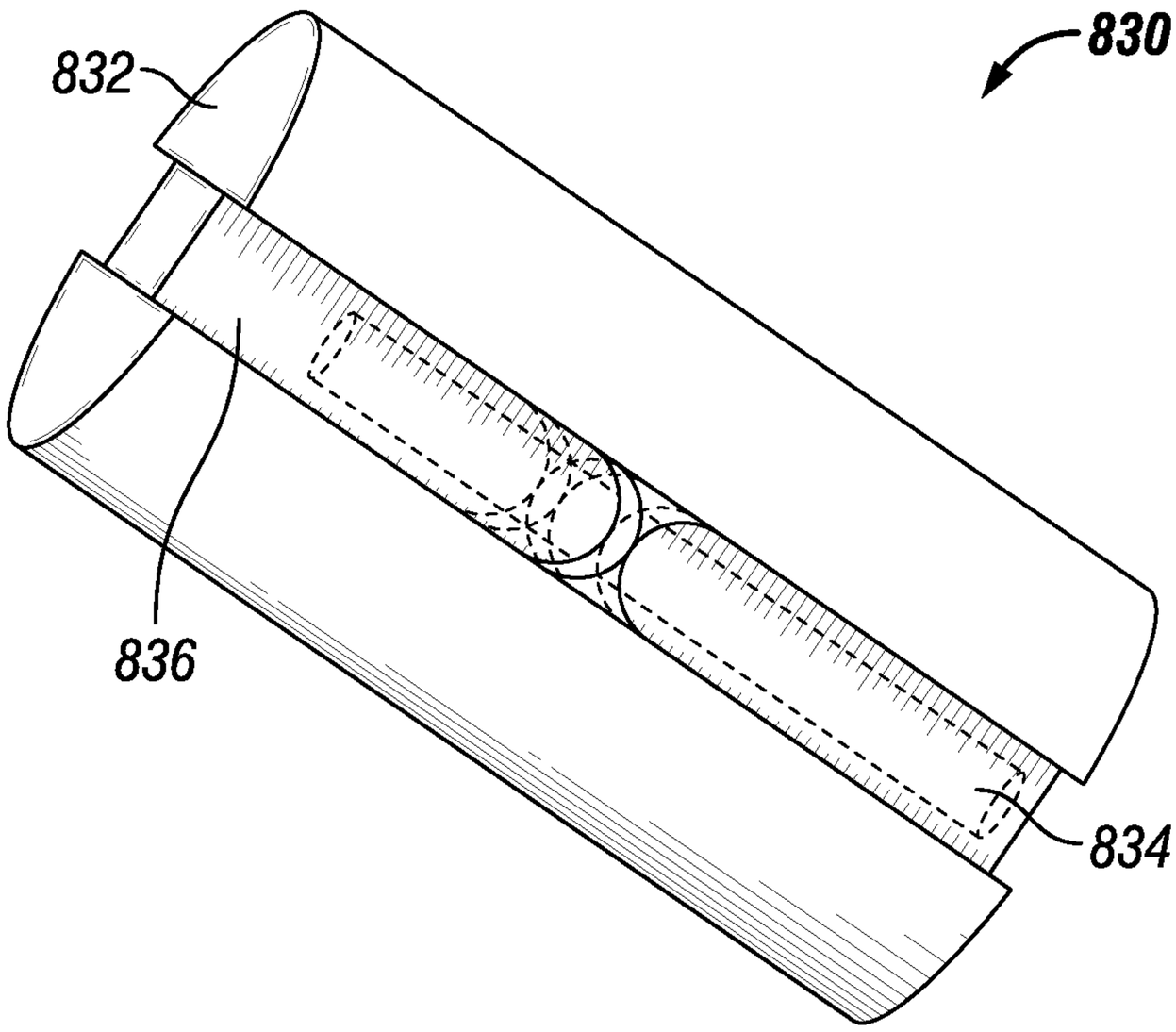

FIG. 9

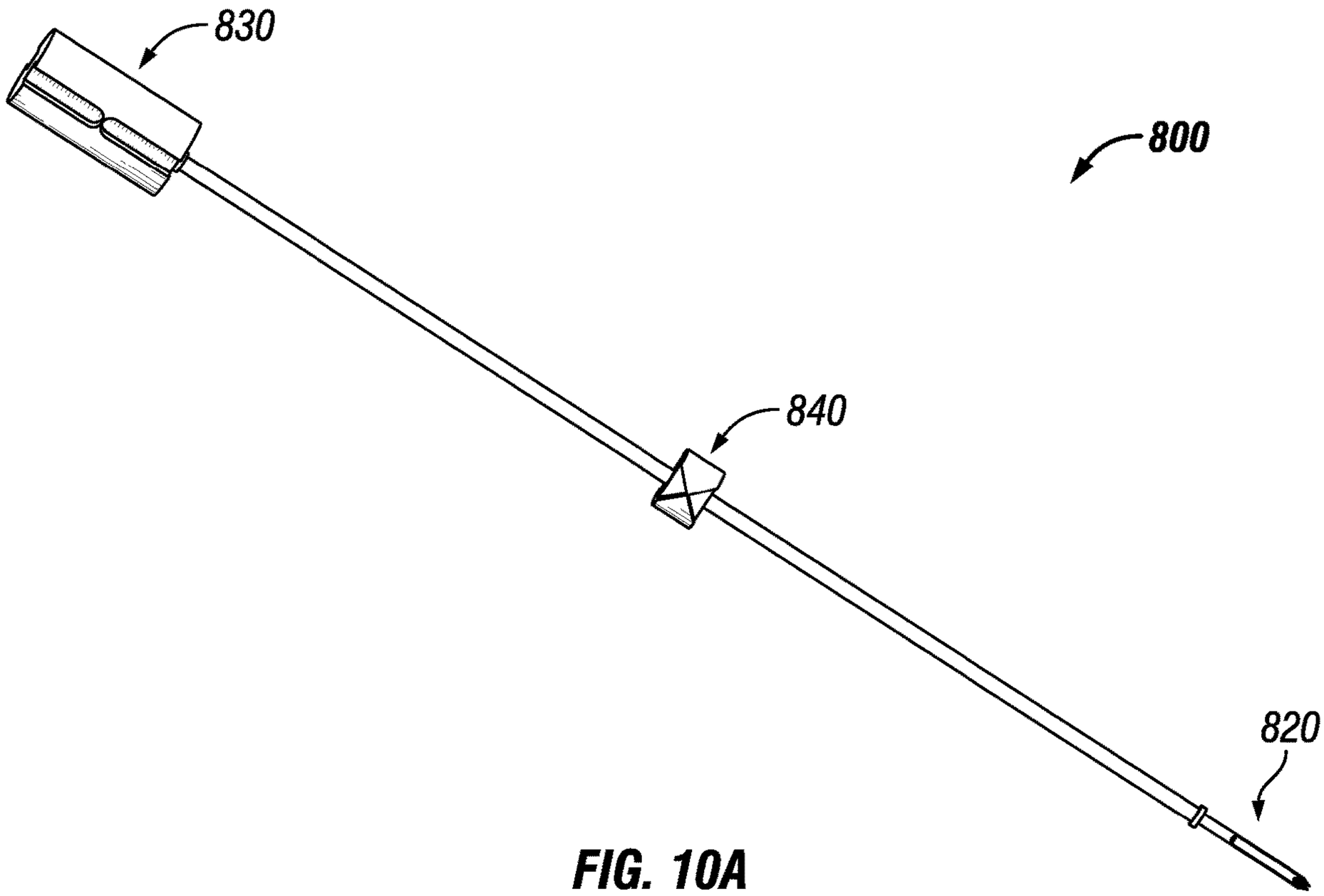

FIG. 10A

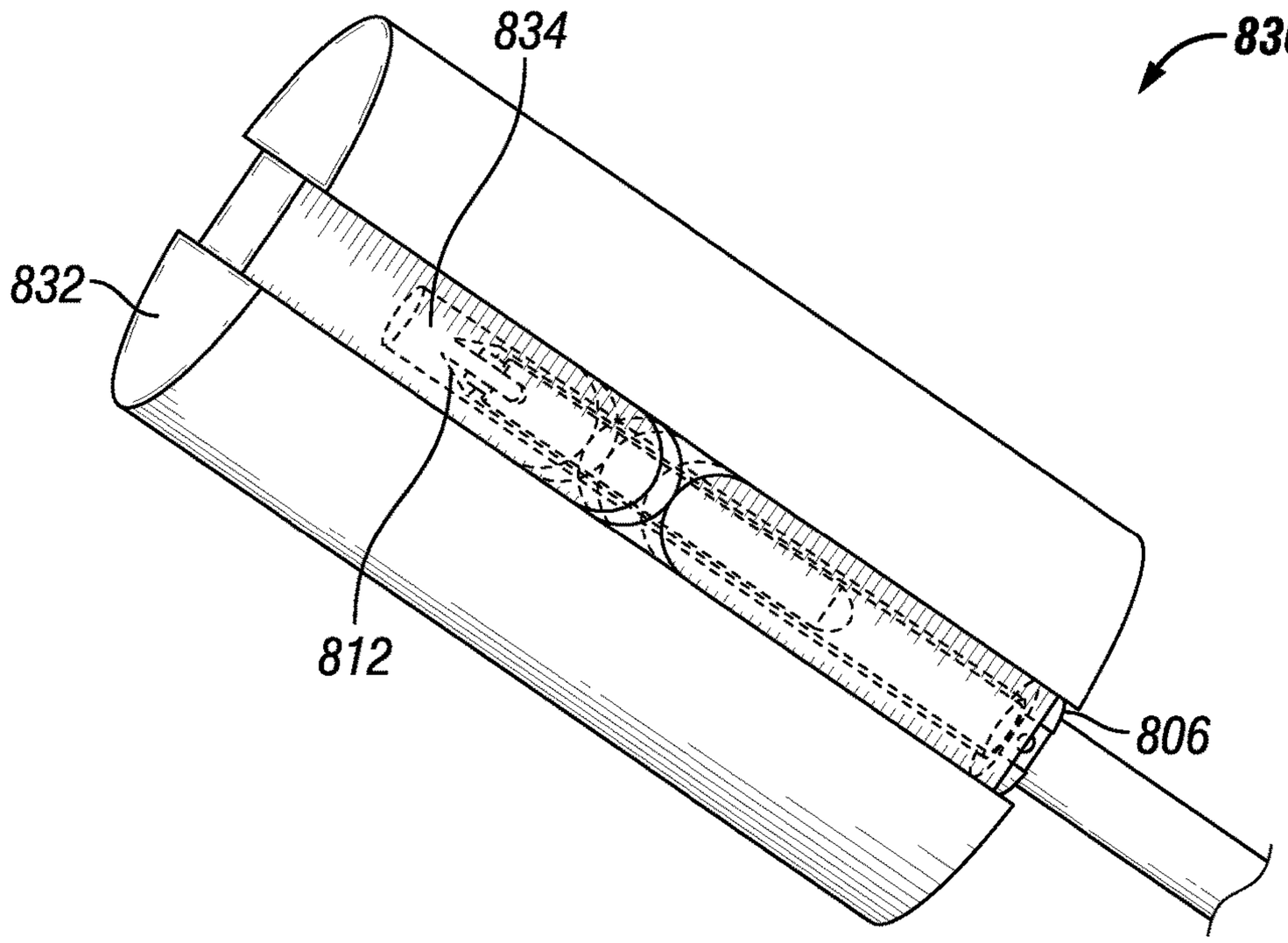

FIG. 10B

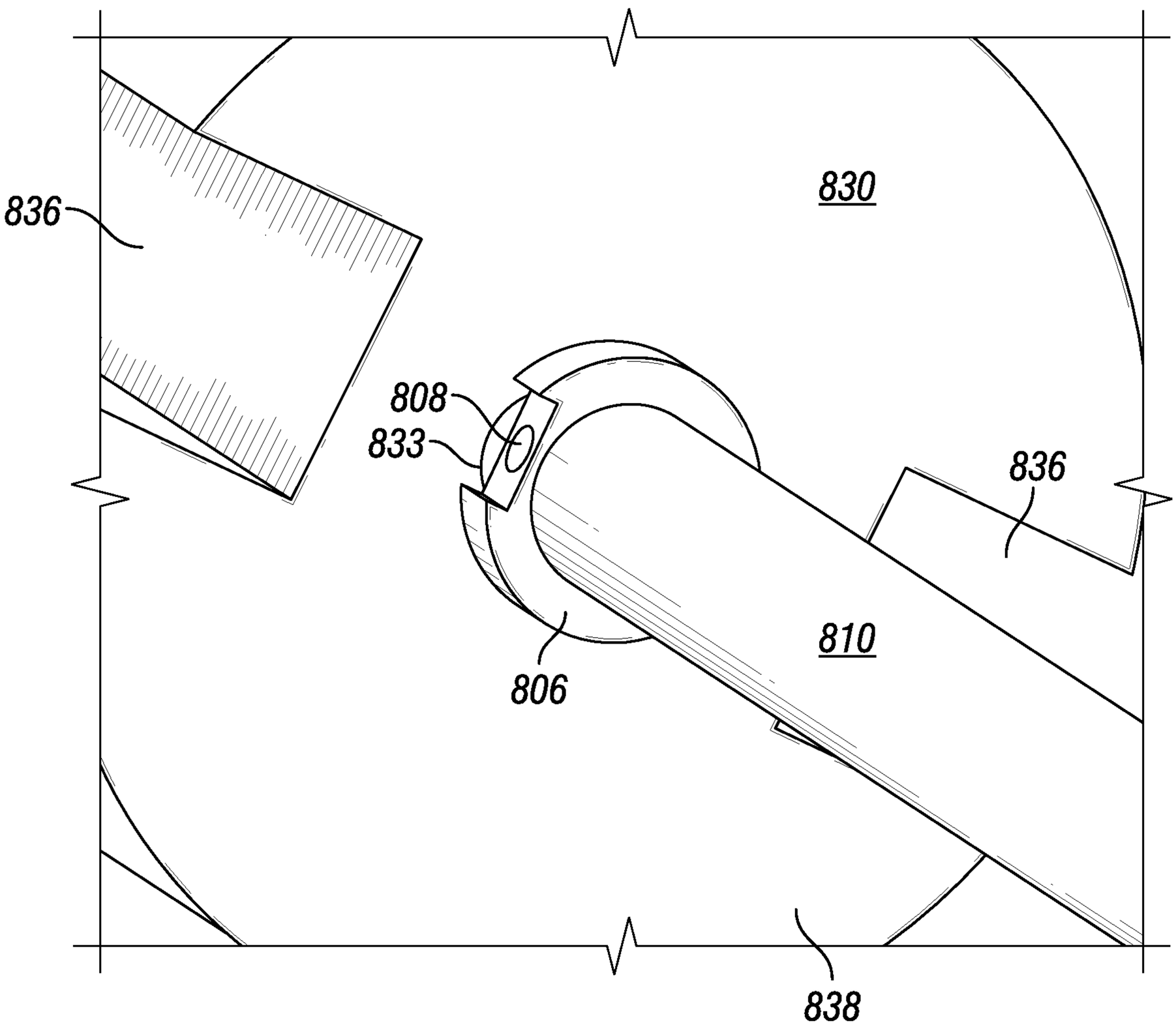

FIG. 10C

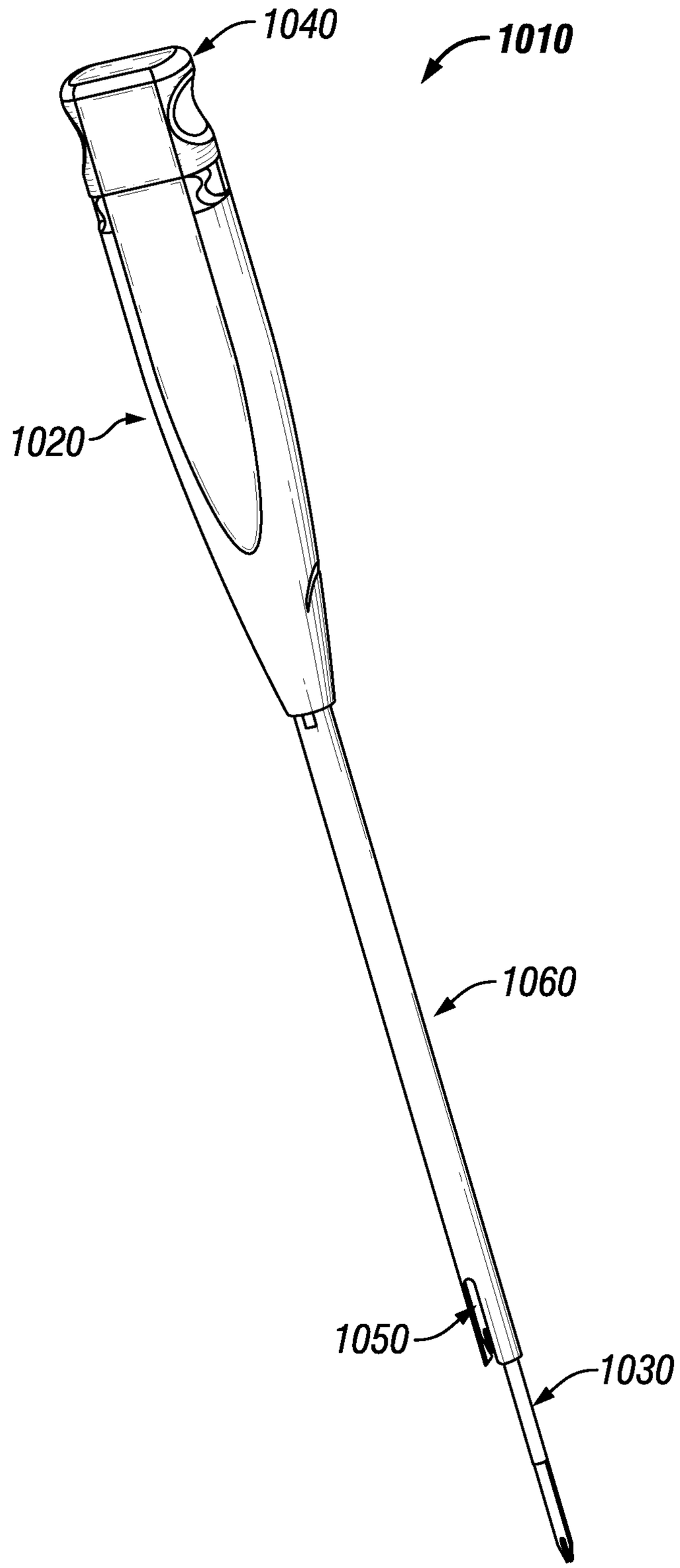

FIG. 11A

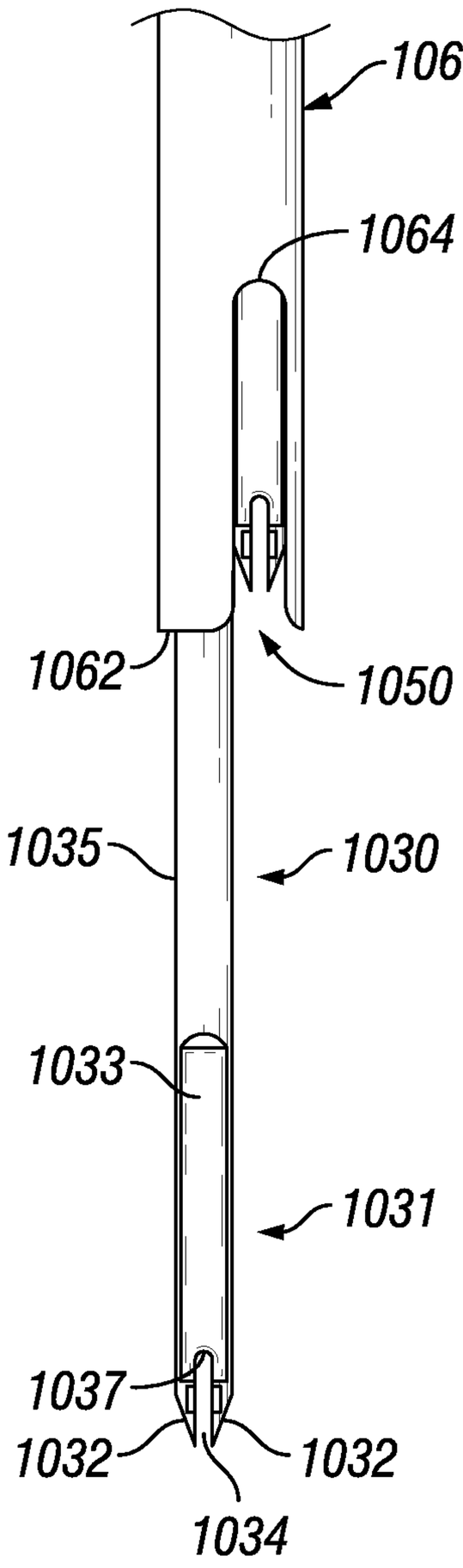

FIG. 11B

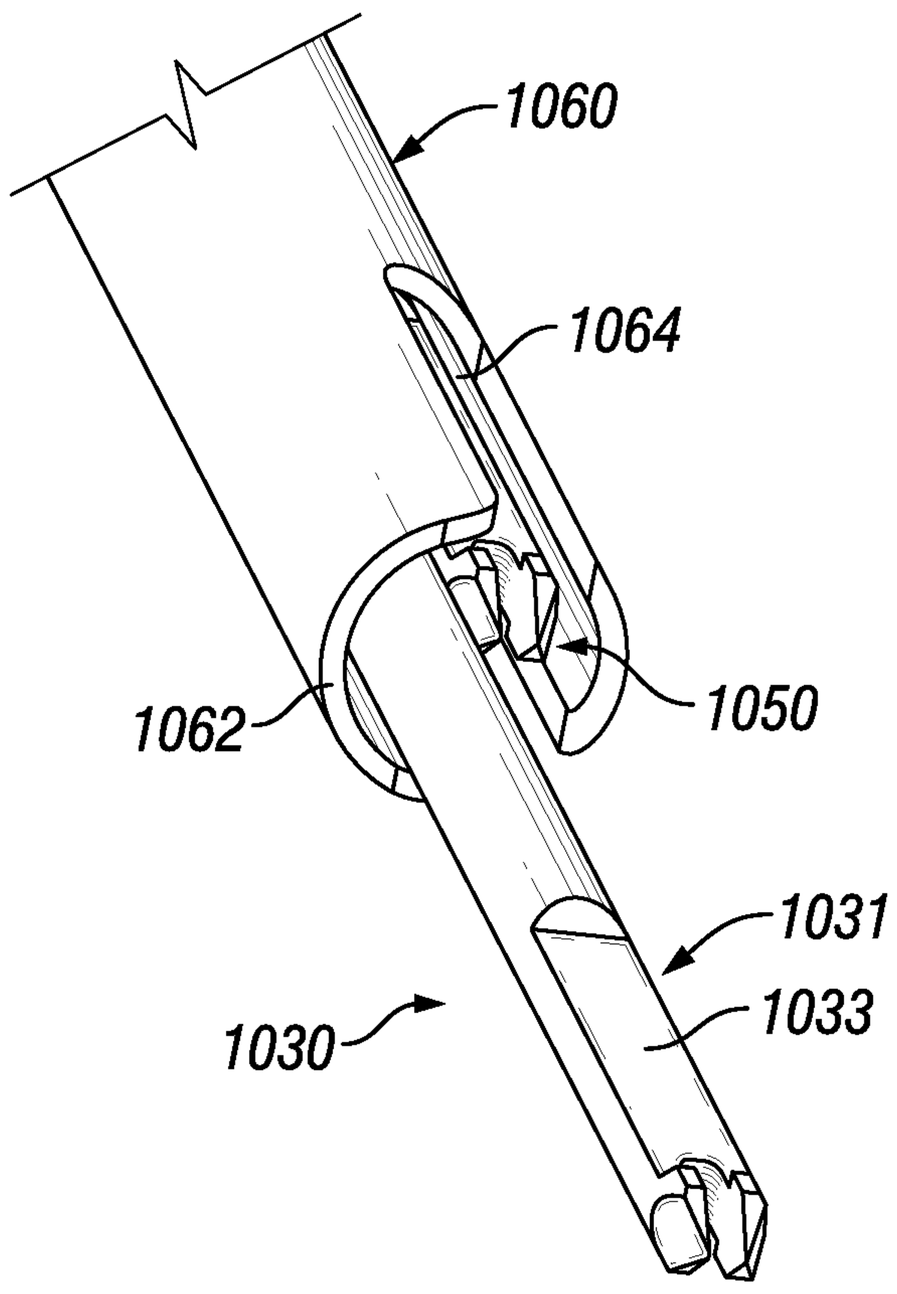

FIG. 11C

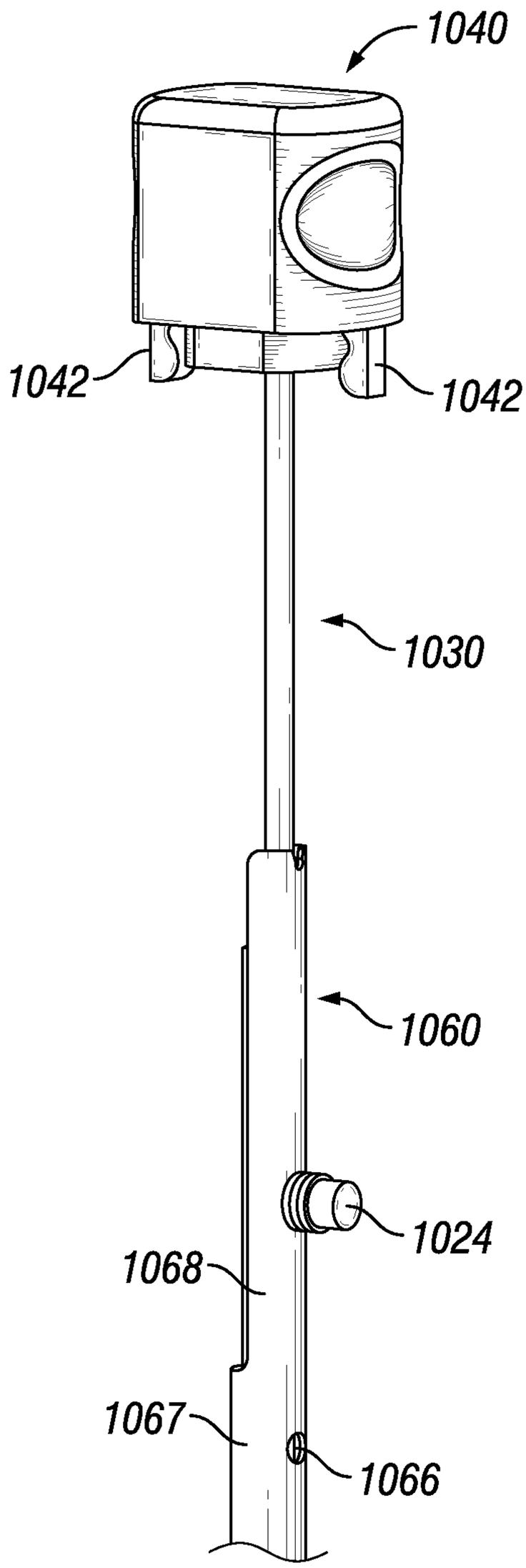

FIG. 11D

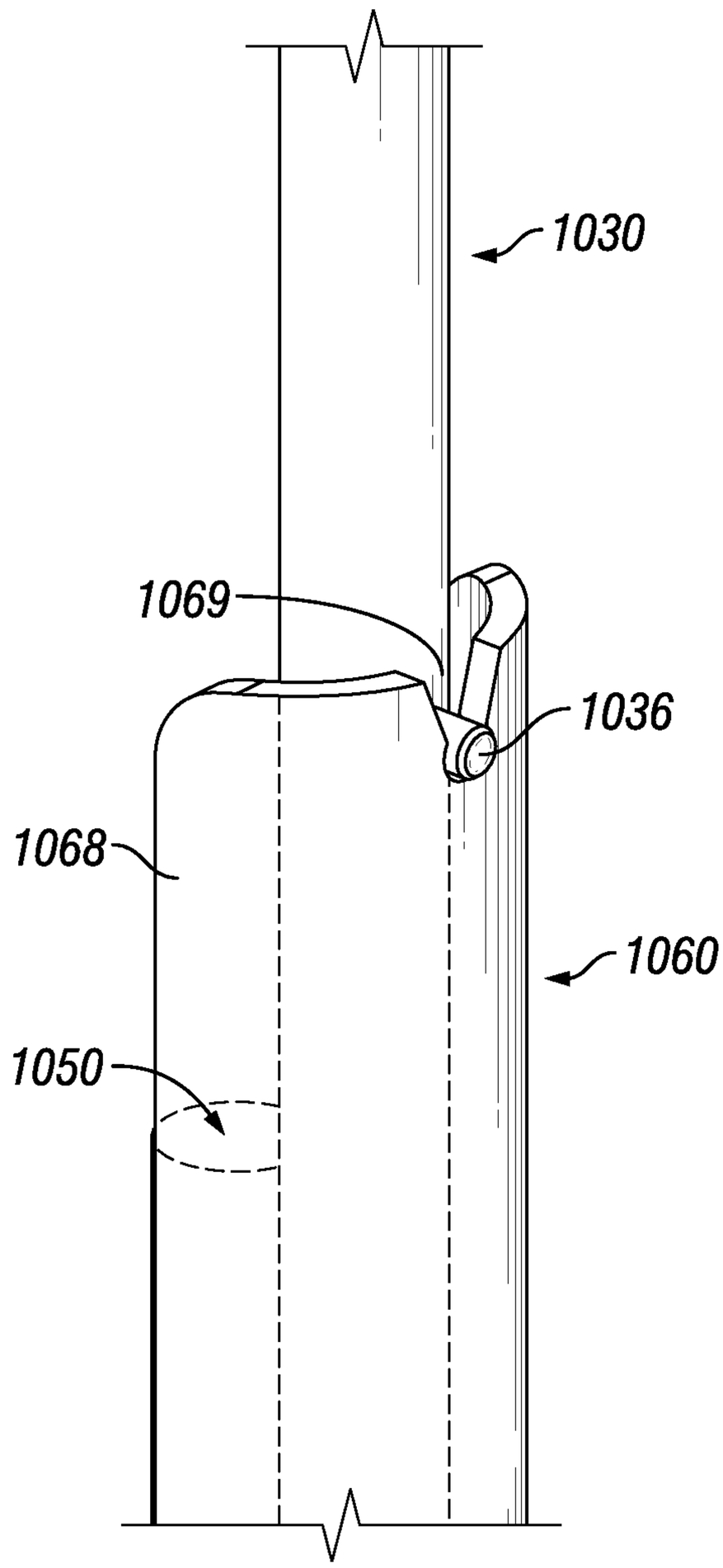

FIG. 11E

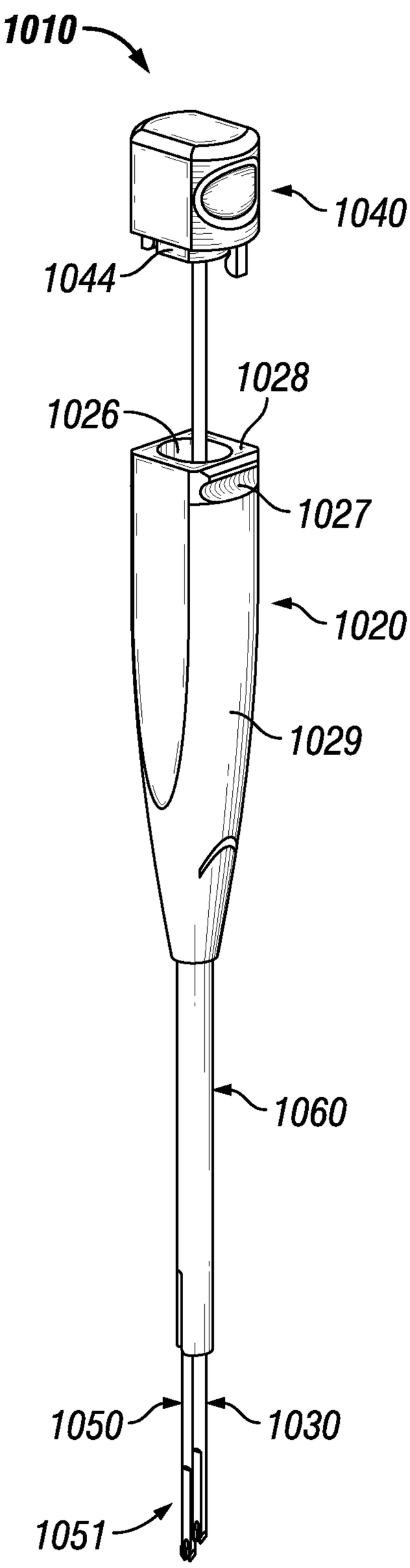

FIG. 12A

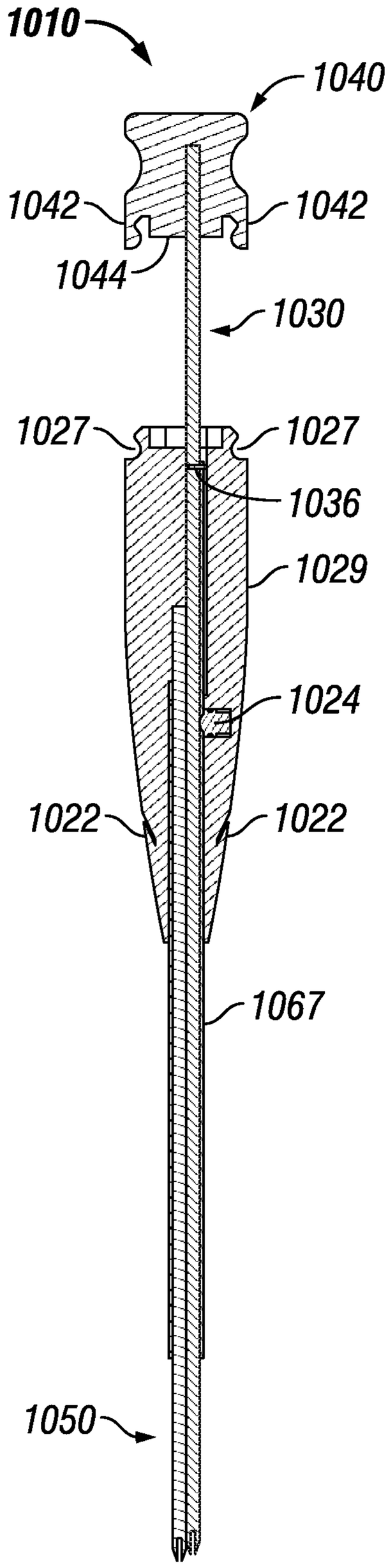

FIG. 12B

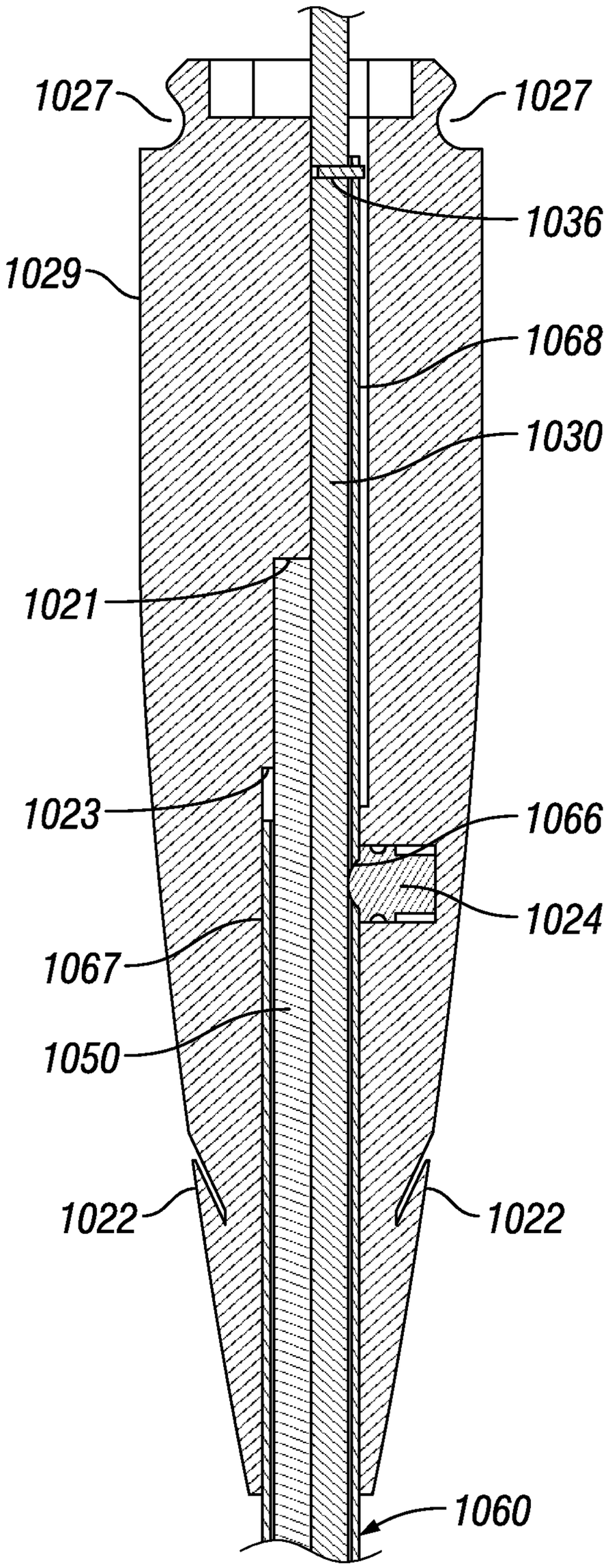
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FIG. 12C

FIG. 13A

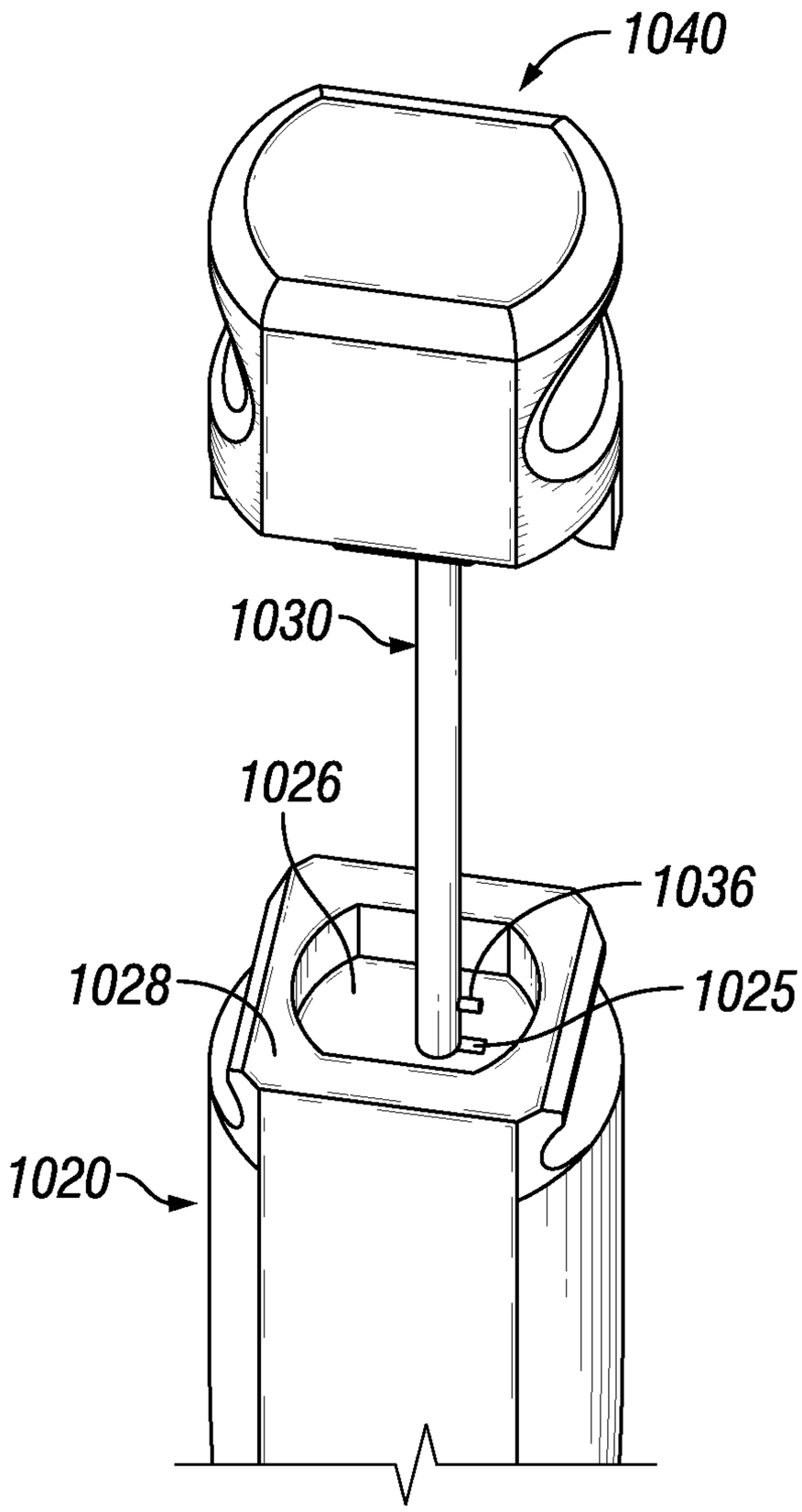

FIG. 13B

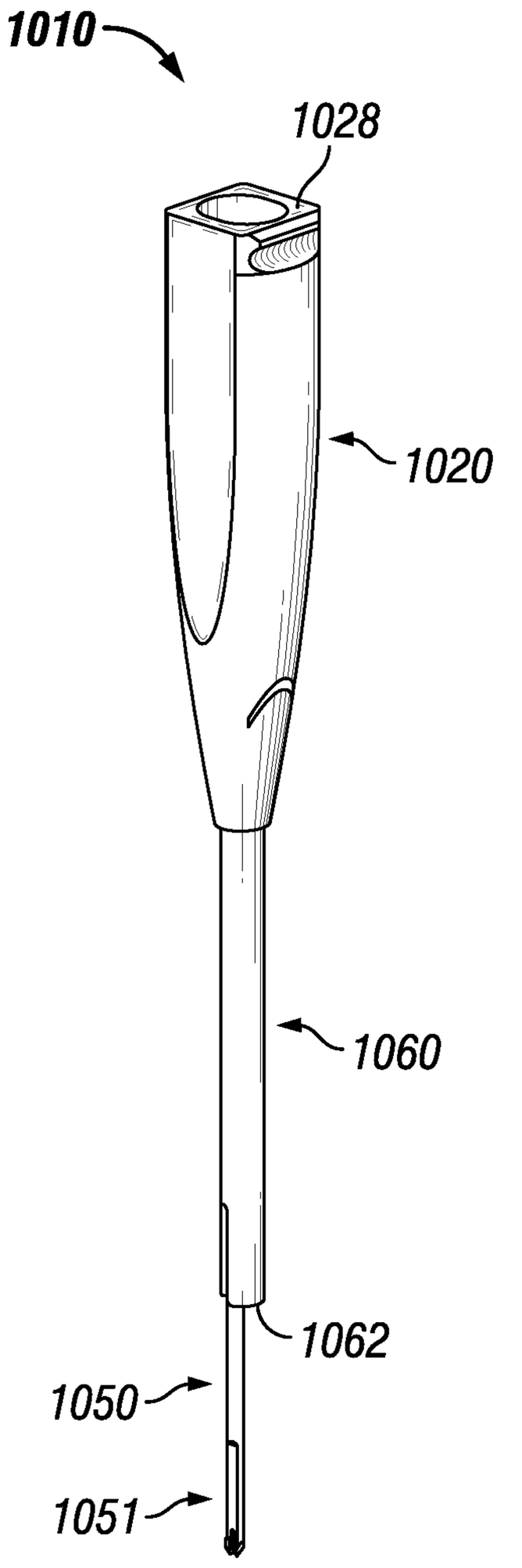

FIG. 14

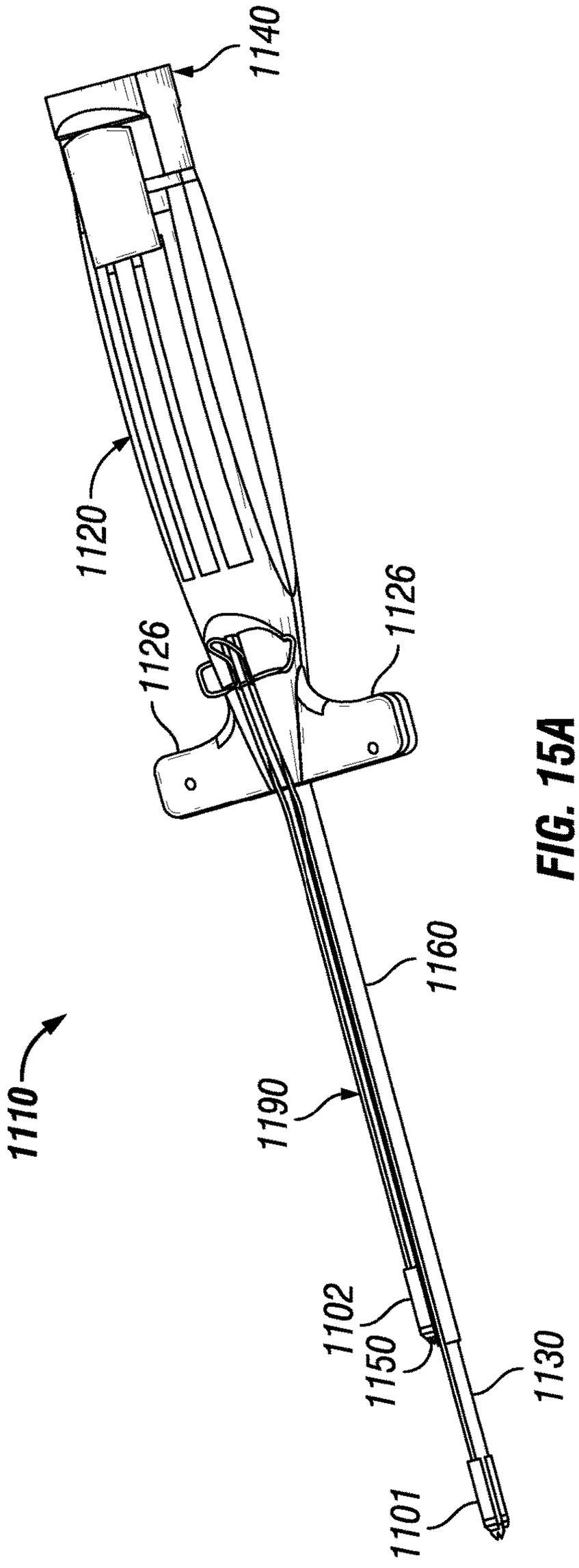

FIG. 15A

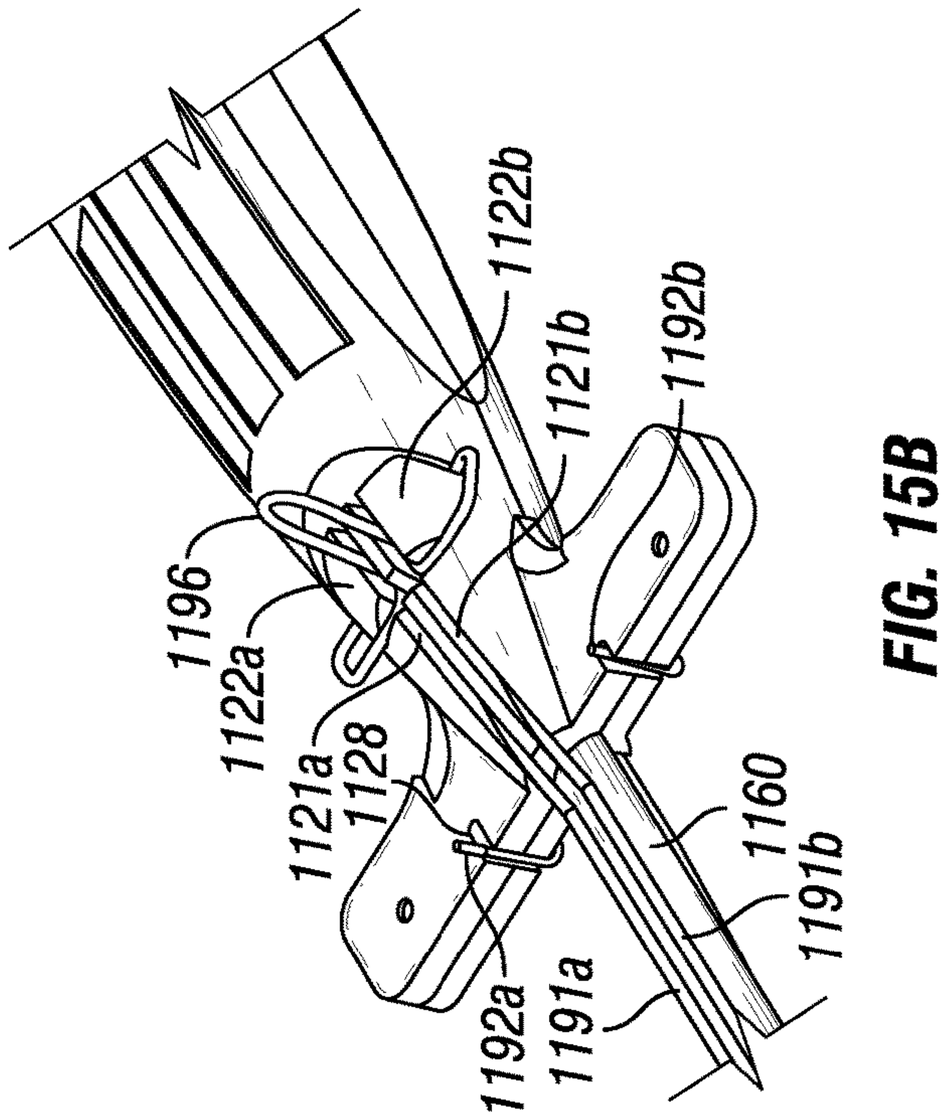

FIG. 15B

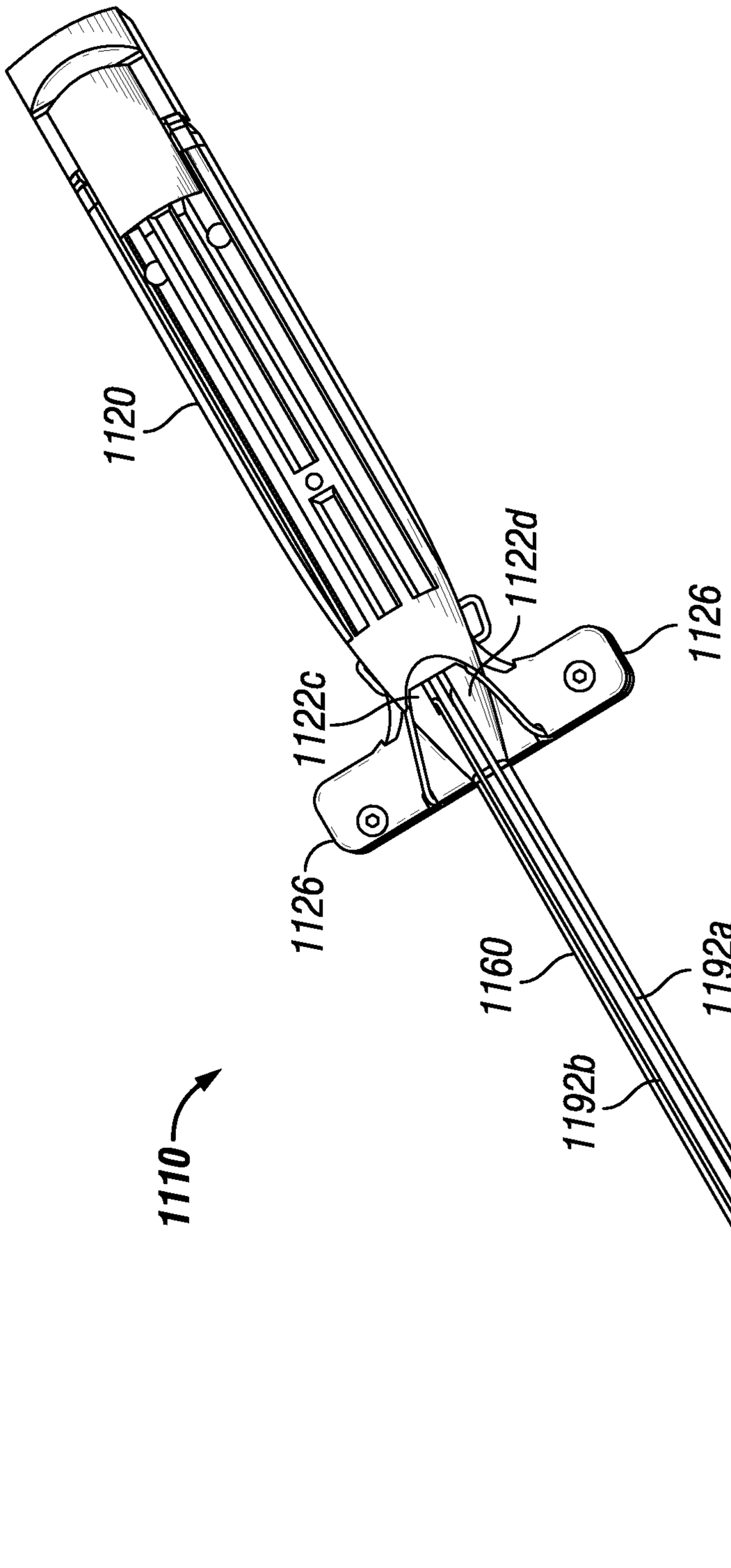

FIG. 15C

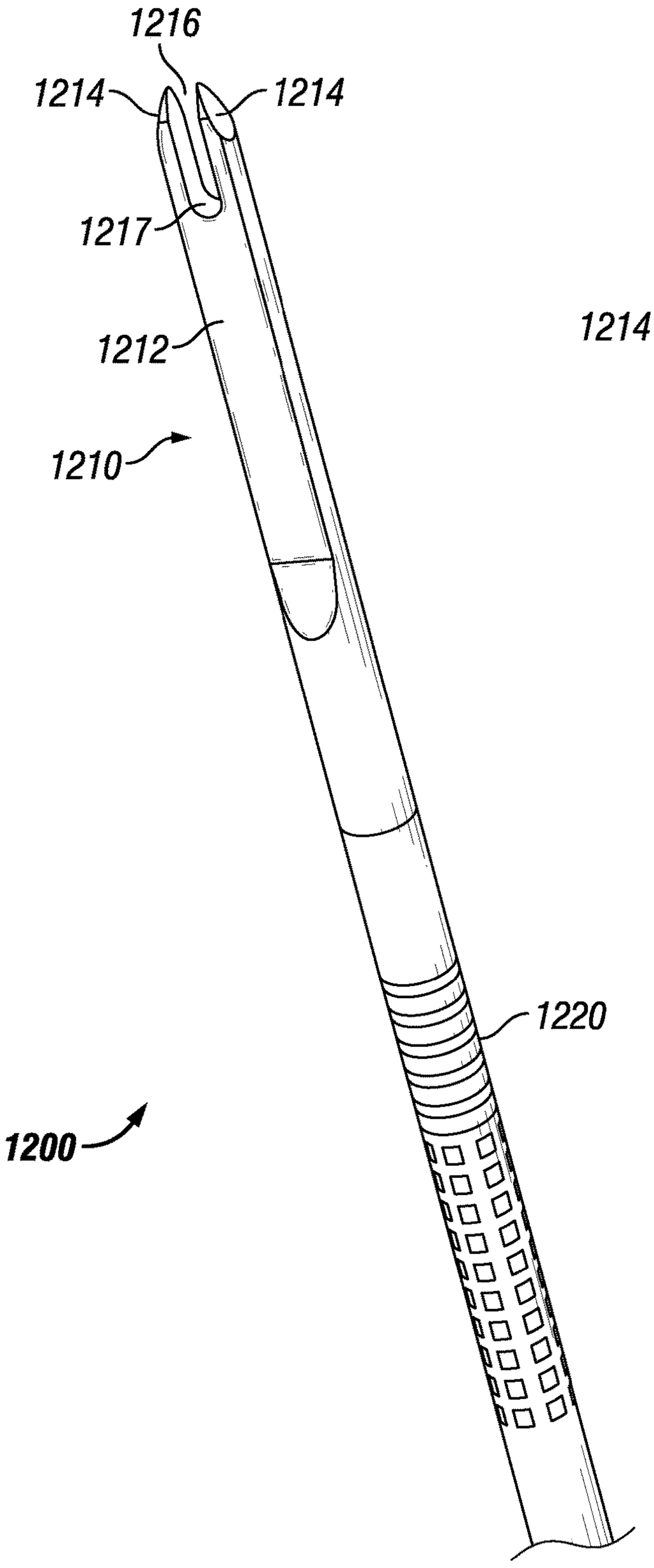

FIG. 16A

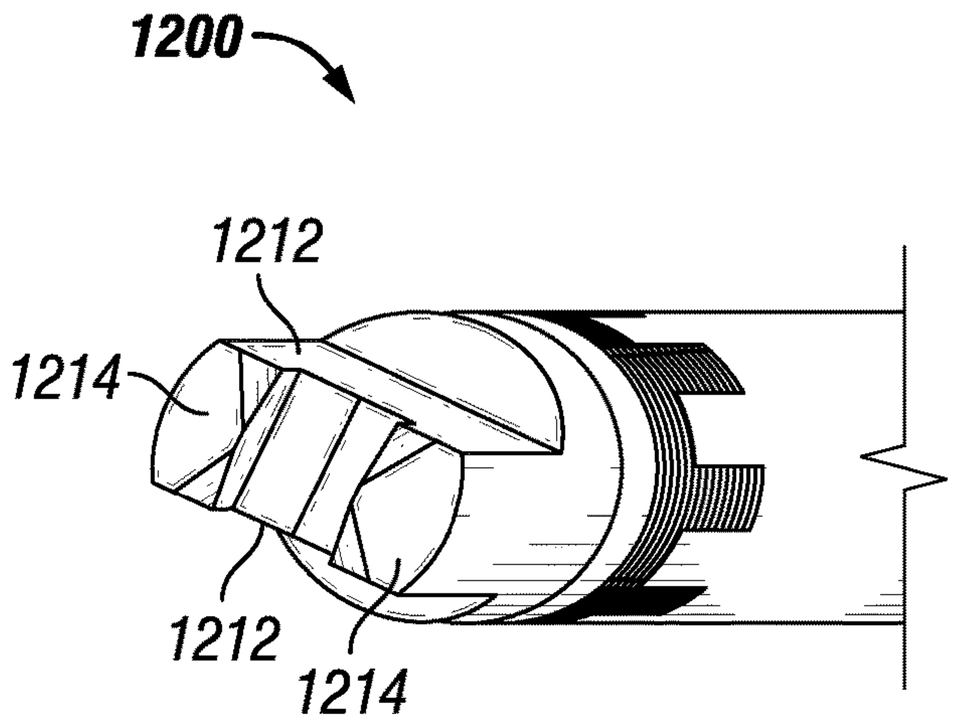

FIG. 16B

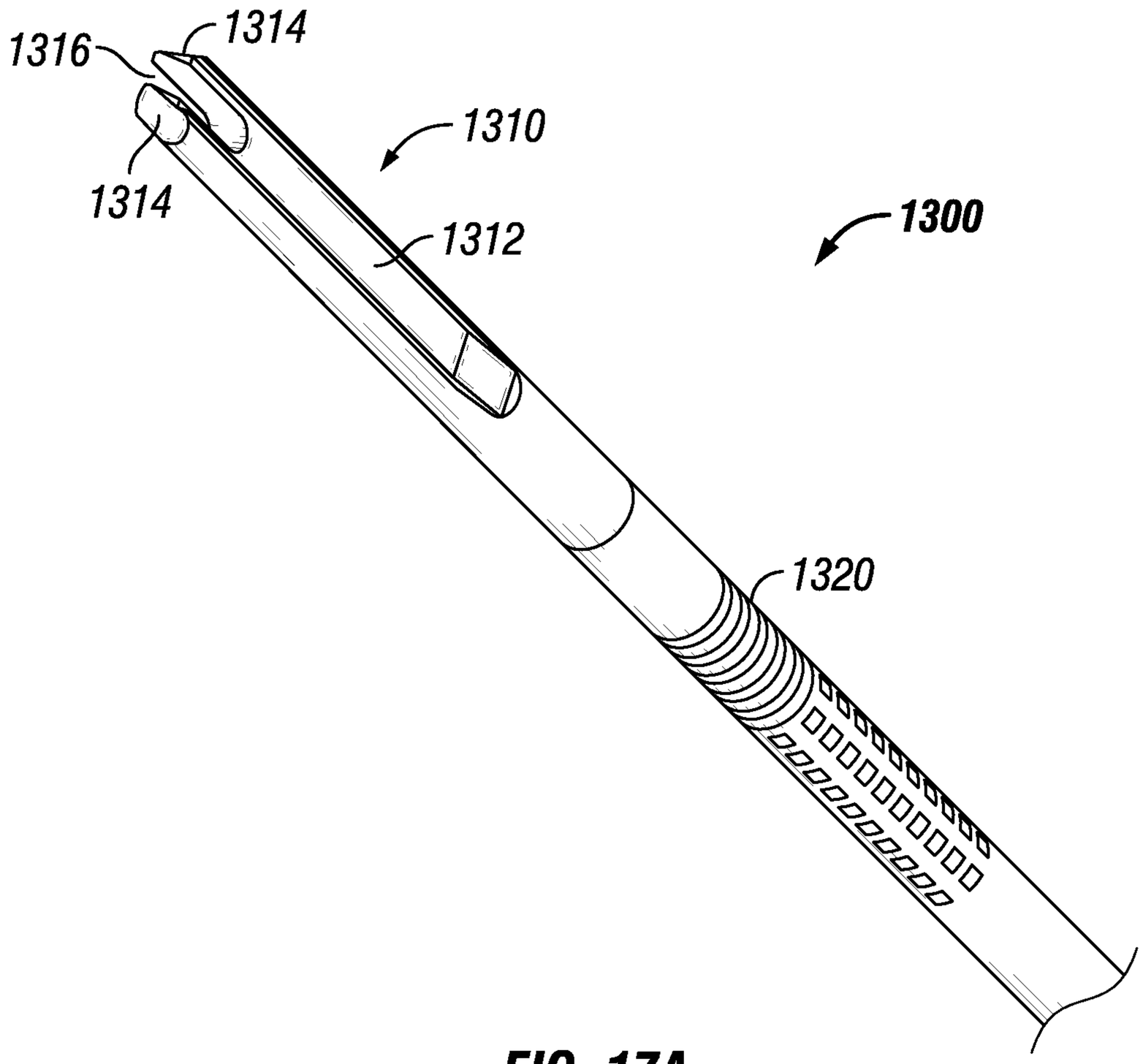

FIG. 17A

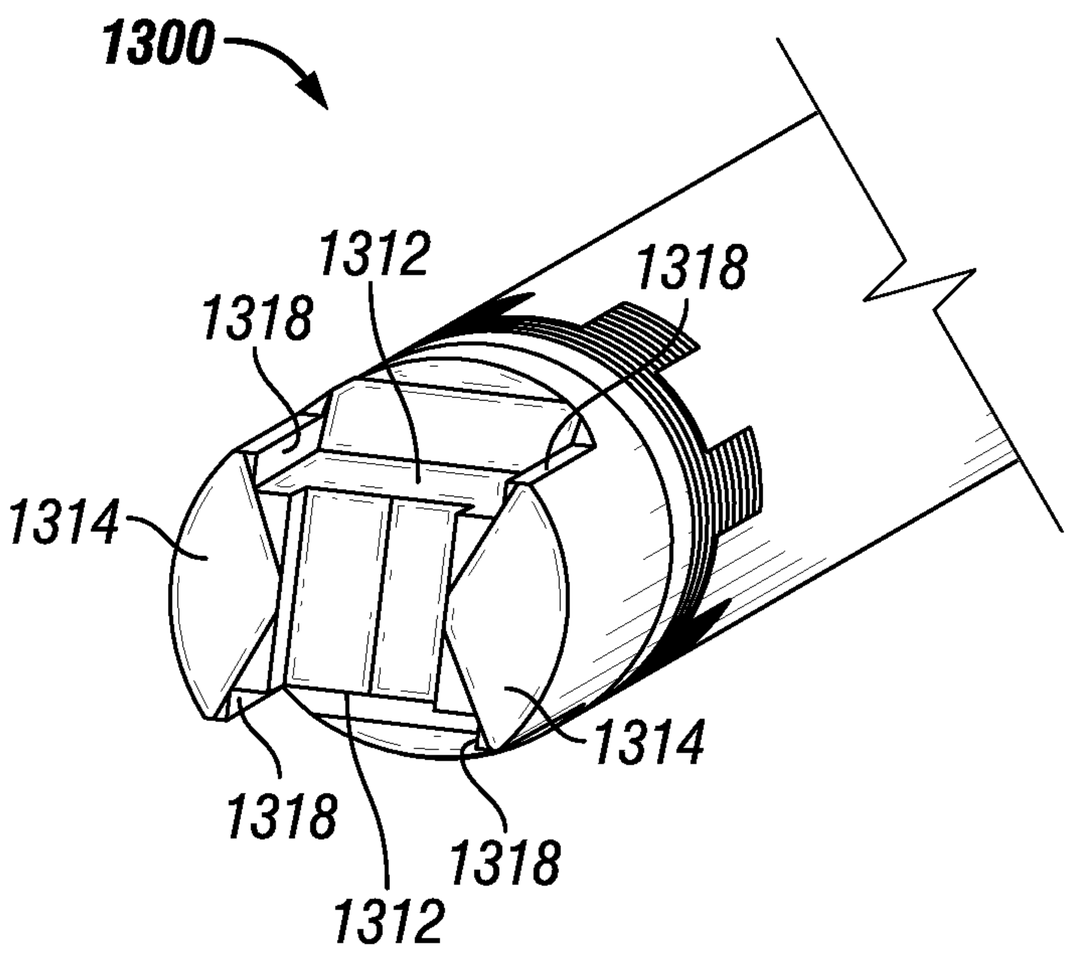

FIG. 17B

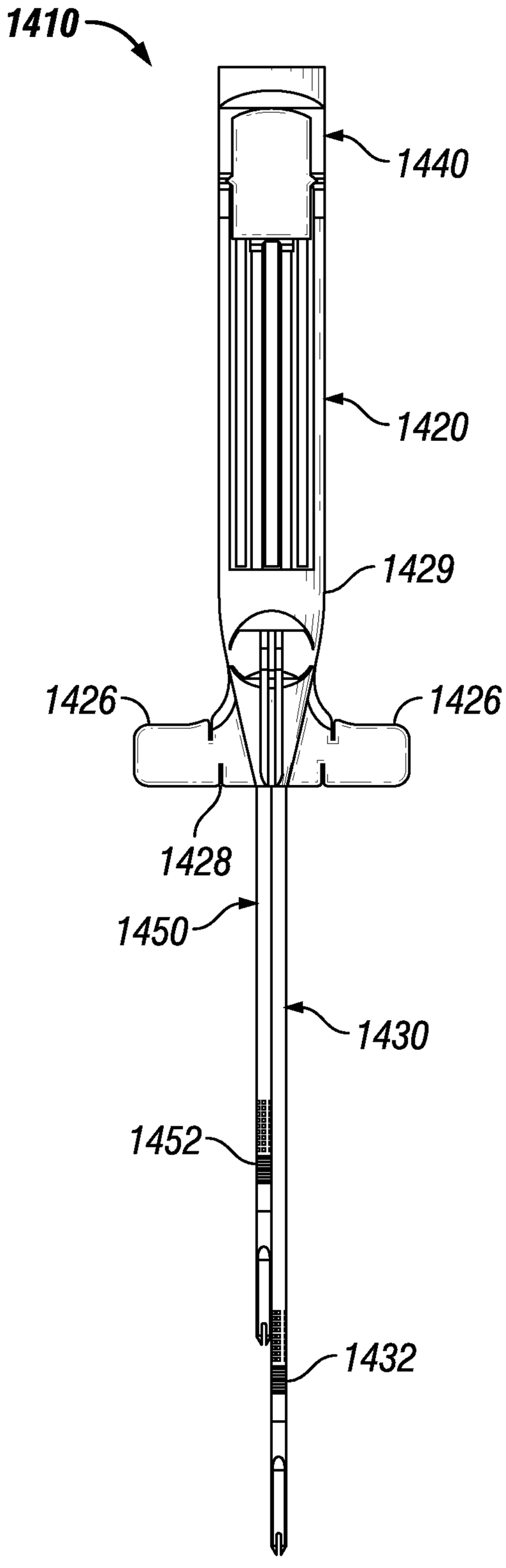
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FIG. 18

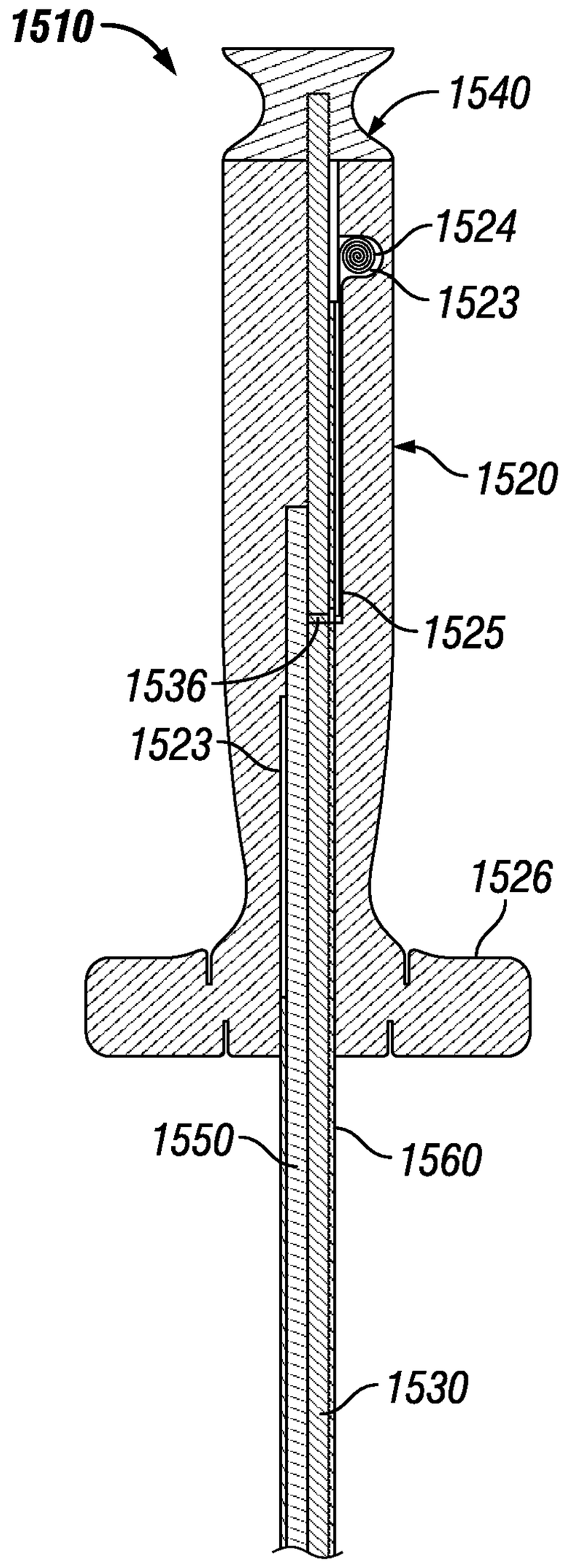
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FIG. 19

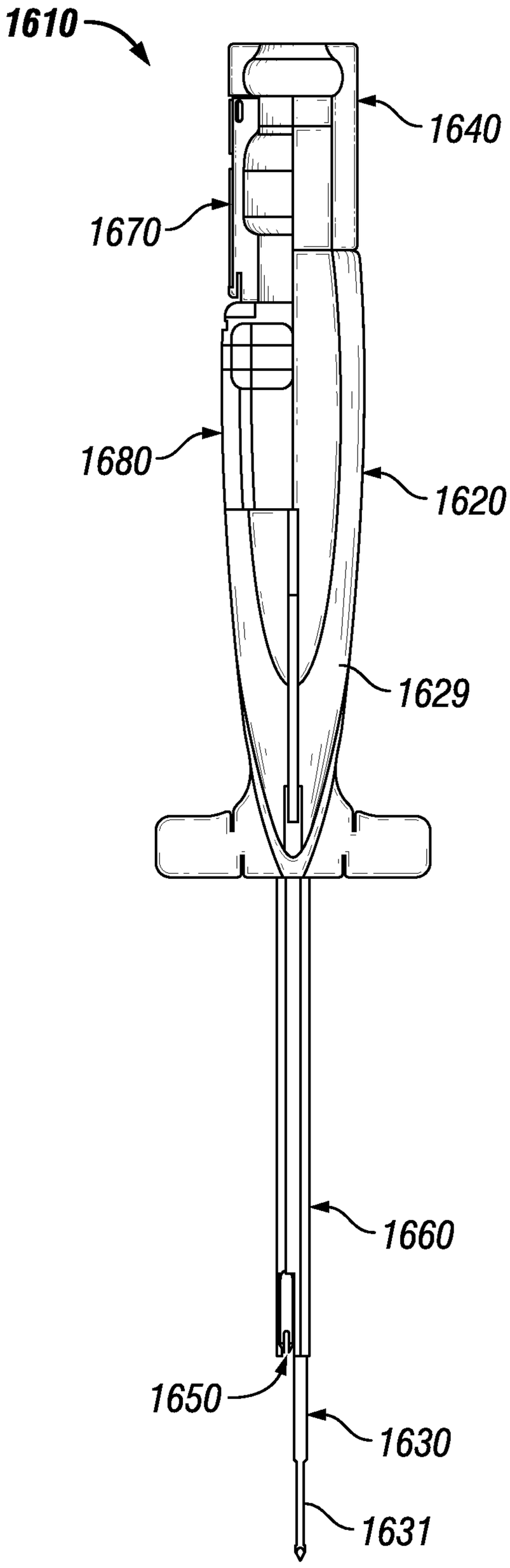

FIG. 20A

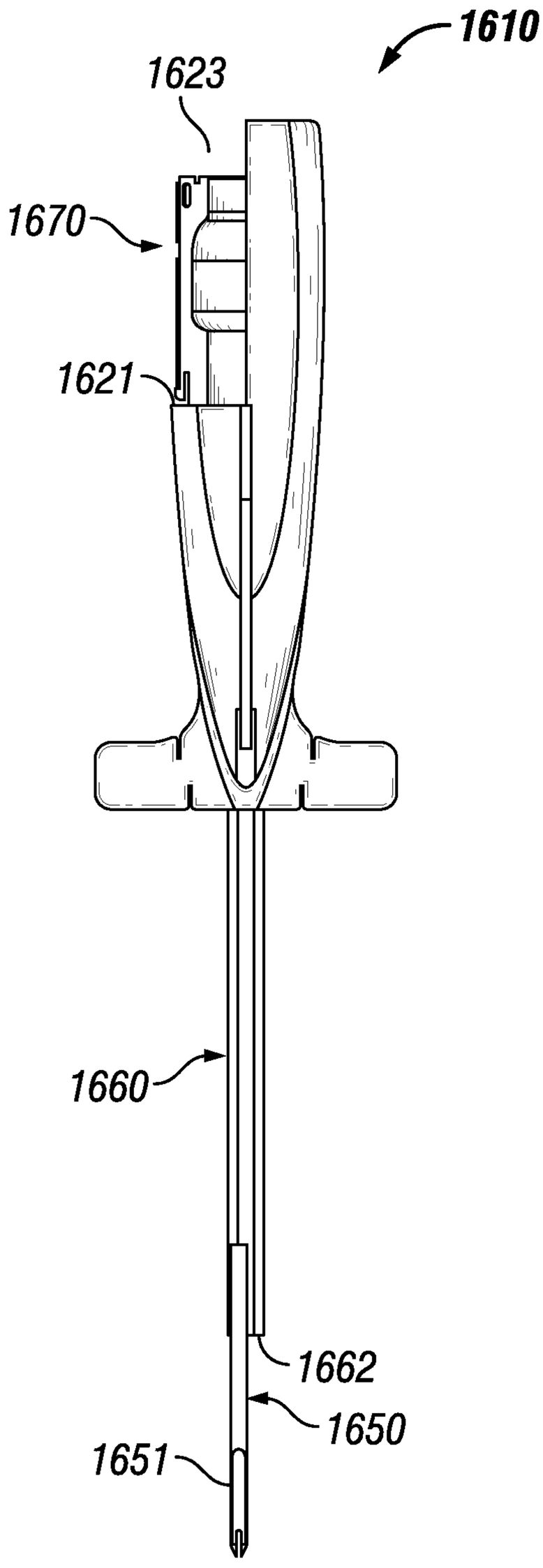

FIG. 20B

INSTRUMENTS AND METHODS OF SOFT TISSUE FIXATION

CROSS-REFERENCE TO RELATED APPLICATION

The present application is a continuation-in-part of U.S. patent application Ser. No. 14/573,538, filed Dec. 17, 2014, the disclosure of which is incorporated herein by referenced.

BACKGROUND OF THE INVENTION

Surgical repair of soft tissue often requires damaged soft tissue or replacement graft tissue to be positioned against adjacent soft tissue or hard tissue (e.g., bony structure). The objective is to form a healing interface so that microscopic connections can be formed during the healing process, thereby adjoining the contacting tissue structures. In order to achieve this objective, it is important to maintain and minimize disruptions at this interface. Otherwise these connections and ultimately the entire repair can be compromised.

In one example, a portion of torn tissue that is typically connected to a bony structure, such as a labrum, rotator cuff, Achilles tendon, patellar tendon, or the like may be connected or reconnected to the bony structure. This is typically achieved by positioning the torn tissue as close to its natural location as possible and anchoring the tissue to the bone. Compression between the bone and tissue is desirable to help maintain the healing interface and to instigate the healing process.

Generally, an anchoring support and a filament attached to the anchoring support are utilized in soft tissue reparation. A surgical knot is typically created to hold the tissue against the bone. However, these surgical knots are subject to loosening, which can reduce or eliminate desirable compression and can lead to undesirable movement of the healing interface, which may result in a suboptimal repair or total failure of the repair.

Despite the use and benefits of such devices and techniques, such devices and techniques can benefit from alternative devices and securement techniques.

BRIEF SUMMARY OF THE INVENTION

In one aspect of the present disclosure, an inserter assembly for inserting anchors into bone includes a handle having a handle body. A sleeve is partially disposed within the handle body and has a passageway extending through the sleeve in a proximal-distal direction. A first inserter is partially disposed within the handle body and the passageway of the sleeve. The first inserter is configured to retain a first anchor for insertion thereof into bone. A second inserter is partially disposed within the handle body and passageway of the sleeve. The first inserter is configured to retain a second anchor for insertion thereof into bone. The inserter assembly has a first configuration in which the sleeve is connected to the first inserter so that the first inserter and sleeve are moveable together relative to the handle body, and a second configuration in which the sleeve is connected to the handle body and disconnected from the first inserter so that the first inserter is moveable relative to the sleeve.

In another aspect of the present disclosure, an inserter assembly for inserting anchors into bone includes a handle having a handle body. A first inserter is disposed within the handle body and is fixedly connected thereto. The first inserter has an insertion end configured to retain a first anchor for insertion thereof into bone. A second inserter is slidably disposed within the handle body and has an insertion end configured to retain a second anchor for insertion thereof into bone.

In a further aspect of the present disclosure, an inserter assembly for soft tissue repair includes an inserter handle having a handle body. A first inserter is slidably disposed within the handle body and has an insertion end extending distally from the handle body. A first anchor defines a passageway extending therethrough and is mounted to the insertion end of the first inserter for insertion thereof into bone. A second inserter is fixedly connected to the handle body and has an insertion end extending distally from the handle body. A second anchor defines a passageway extending therethrough and is mounted to the insertion end of the second inserter for insertion thereof into bone. A sleeve is slidably disposed within the handle body and positioned about respective portions of the first and second inserters. The sleeve is moveable relative to the second inserter between a first and second position. A length of filament extends through the passageways of the first and second inserters.

BRIEF DESCRIPTION OF THE DRAWINGS

The features, aspects, and advantages of the present invention will become better understood with regard to the following description, appended claims, and accompanying drawings in which:

FIG. **1**A illustrates one embodiment of a tissue fixation assembly.

FIGS. **1**B and **1**C are schematic side views of a configuration of the fixation assembly of FIG. **1**A.

FIGS. **1**D and **1**E are schematic top views of the configuration of the fixation assembly of FIG. **1**A.

FIG. **2**A illustrates another embodiment of a tissue fixation assembly.

FIGS. **2**B and **2**C are schematic side views of a configuration of the tissue fixation assembly of FIG. **2**A.

FIG. **2**D is a schematic top view of the configuration of the fixation assembly of FIG. **2**A.

FIG. **3**A illustrates a further embodiment of a tissue fixation assembly.

FIGS. **3**B and **3**C are schematic side views of a configuration of the tissue fixation assembly of FIG. **3**A.

FIGS. **3**D and **3**E are schematic top views of the configuration of the tissue fixation assembly of FIG. **3**A.

FIG. **4**A illustrates yet another embodiment of a tissue fixation assembly.

FIG. **4**B is a cross-sectional schematic view of the tissue fixation assembly of FIG. **4**A taken at **4**B-**4**B.

FIG. **4**C is a schematic side view of a configuration of the tissue fixation assembly of FIG. **4**B.

FIGS. **4**D and **4**E are schematic top views of the configuration of the tissue fixation assembly of FIG. **4**A.

FIG. **5**A illustrates still another embodiment of a tissue fixation assembly that includes a sleeve and a length of filament.

FIG. **5**B illustrates exemplary braiding patterns of the length of filament of FIG. **5**A.

FIG. **5**C is a schematic side view of a configuration of the tissue fixation assembly of FIG. **5**A.

FIGS. **5**D and **5**E are schematic top views of a first arrangement of the tissue fixation assembly of FIG. **5**A and configuration of FIG. **5**C.

FIG. **6**A illustrates yet a further embodiment of a tissue fixation assembly.

FIG. **6**B illustrates one embodiment of an inserter device.

FIG. **6**C is a schematic side view of an exemplary configuration of the tissue fixation assembly of FIG. **6**A employing inserter device of FIG. **6**B.

FIGS. **6**D and **6**E are schematic top views of the configuration of the tissue fixation assembly of FIGS. **6**A and **6**C.

FIG. **7** illustrates an alternative embodiment inserter device.

FIG. **8**A is a front view of another embodiment inserter device.

FIG. **8**B is a side view of the inserter device of FIG. **8**A.

FIG. **8**C is an enlarged view of dashed circle **8**C of FIG. **8**A.

FIG. **8**D is an enlarged view of dashed circle **8**D of FIG. **8**B.

FIG. **9** is a perspective view of one embodiment of a cap.

FIG. **10**A is a perspective view of an assembly including the inserter of FIG. **8**A and cap of FIG. **9**.

FIG. **10**B is an enlarged side perspective view of the assembly of FIG. **10**A.

FIG. **10**C is an enlarged bottom perspective view of the assembly of FIG. **10**A.

FIG. **11**A is a perspective view of an inserter assembly according to another embodiment of the present disclosure being depicted in a first insertion configuration.

FIG. **11**B is an enhanced front view of a distal end of the inserter assembly of FIG. **11**A.

FIG. **11**C is an enhanced bottom perspective view of the distal end of the inserter assembly of FIG. **11**A.

FIG. **11**D is a partial perspective view of first and second inserters, a sleeve, and a ball detent of inserter assembly of FIG. **11**A.

FIG. **11**E is an enhanced partial transparent view of the first and second inserters and sleeve of FIG. **11**D.

FIG. **12**A is a perspective view of the inserter assembly of FIG. **11**A being depicted in one stage of a transition phase thereof.

FIG. **12**B is a cross-sectional view taken of the inserter of FIG. **12**A taken along a midline thereof.

FIG. **12**C is an enhanced view of FIG. **12**B.

FIG. **13**A is a perspective view of the inserter assembly of FIG. **11**A being depicted in another stage of the transition phase thereof.

FIG. **13**B is an enhanced top perspective view of the inserter assembly of FIG. **13**A.

FIG. **14** is a perspective view of the inserter assembly of FIG. **11**A being depicted in a second insertion configuration.

FIG. **15**A is a front perspective view of an inserter assembly according to a further embodiment of the present disclosure.

FIG. **15**B is an enhanced perspective view of the inserter assembly of FIG. **15**A.

FIG. **15**C is rear perspective view of the inserter assembly of FIG. **15**A.

FIG. **16**A is a front perspective view of an inserter according to another embodiment of the present disclosure.

FIG. **16**B is a top perspective view of the inserter of FIG. **16**A.

FIG. **17**A is a front perspective view of an inserter according to yet another embodiment of the present disclosure.

FIG. **17**B is a top perspective view of the inserter of FIG. **17**A.

FIG. **18** is a front view of an inserter assembly according to a still further embodiment of the present disclosure.

FIG. **19** is cross-sectional view an inserter assembly according to an even further embodiment of the present disclosure taken along a midline thereof.

FIG. **20**A is a front view of an inserter assembly according to yet another embodiment of the present disclosure being depicted in a first insertion configuration.

FIG. **20**B is a front view of the inserter assembly of FIG. **20**A being depicted in a second insertion configuration.

DETAILED DESCRIPTION

The fixation devices, assemblies, systems, and associated methods of use of the present invention are intended for use in the repair, reattachment, replacement, or otherwise securement of tissue, including both hard tissue (e.g., bone or the like) and soft tissue. Soft tissue may be, for example, meniscus, cartilage, capsule, ligaments and tendons, replacement grafts of any of these soft tissues, or the like. While many of the exemplary methods disclosed herein are directed towards the use of fixation assemblies, systems, and methods involving a filament/suture anchor for implantation into a bone hole, it is envisioned that such assemblies, systems, and methods described herein can be utilized with a hard/solid anchor in lieu of or in conjunction with a filament/suture anchor. In addition, it should be understood that the following devices and methods may be utilized in both open surgery and arthroscopic surgery.

As used herein unless stated otherwise, the term "anterior" means toward the front part of the body or the face, the term "posterior" means toward the back of the body. The term "medial" means closer to or toward the midline of the body, and the term "lateral" means further from or away from the midline of the body.

Also, when referring to specific directions in the following discussion of certain device, the terms "proximal" and "distal" are to be understood in regard to the device's orientation and position during exemplary application to human body. Thus, as used herein, the term "proximal" means closer to the operator or in a direction toward the operator, and the term "distal" means more distant from the operator or in a direction away from the operator.

In addition, the terms "about," "generally" and "substantially" are intended to mean that slight deviations from absolute are included within the scope of the term so modified.

Also, as used herein, the term "filament" or "filamentary" is defined as a suture or other thread-like material. Such filaments may be constructed of synthetic material (e.g., PLGA, UHMWPE (ultra high molecular weight polyethylene), polyester, PEEK, nylon, polypropylene, aramids (for example Kevlar®-based fibers) or the like, or blends thereof), organic material (silk, animal tendon, or the like or blends thereof), or blends of both one or more organic materials and one or more synthetic materials. Alternatively, filaments may include thin metal wires. While any of these materials may be used, it is preferable, and is disclosed herein, that the various filaments or filamentary aspects of the present invention be constructed out of suture, such as UHMWPE, polyester or blends thereof.

FIG. **1**A depicts an embodiment of a fixation assembly **10**. Fixation assembly **10** includes a filamentary sleeve **12** and a length of filament **20**. Sleeve **12** includes a first opening and a second opening **16** and a passageway extending therethrough. In one example, the sleeve **12** can be the Iconix® all suture anchor system (Stryker Corporation, Kalamazoo, Mich.). Other configurations are also envisioned, examples of which are disclosed in U.S. application Ser. No. 13/783,

804, filed Mar. 4, 2013; Ser. No. 13/303,849, filed Nov. 23, 2011; Ser. No. 13/588,586, filed Aug. 17, 2012; Ser. No. 13/588,592, filed Aug. 17, 2012; Ser. No. 14/104,677, filed Dec. 12, 2013; Ser. No. 14/298,295, filed Jun. 6, 2014; and U.S. Pat. Nos. 5,989,252 and 6,511,498, the entireties of which are incorporated by reference herein as if fully set forth herein and all of which are assigned to the same entity as the present invention.

Filament **20** is folded over itself at a location along its length to form a loop **26** that defines a loop-end of filament **20** and an apex **28**. Filament **20** is disposed at least partially within the passageway of the sleeve **12** such that the loop-end extends from one end of sleeve **12** and first and second free ends **22** and **24** of filament **20** extend from the opposite end of sleeve **12**.

FIGS. **1**B-**1**D depict an embodiment method of using fixation assembly **10**. This method may be utilized in many procedures in which soft tissue is to be attached or otherwise anchored to bone. For ease of illustration, the various disclosed exemplary methods and uses throughout will be described with reference to a rotator cuff repair, though these methods and uses may be translated to other soft tissue repairs. In such a method, a bone hole **52** is drilled or otherwise formed in bone **50**. An inserter device (not shown) may be attached to sleeve **12** such that sleeve **12** and inserted into bone hole **52** as shown in FIGS. **1**B and **1**C. At this point, the loop-end and first and second free ends **22** and **24** extend from bone hole **52** and are tensioned to seat sleeve **12** into an anchoring position within bone hole **52**.

With the loop-end and free ends **22**, **24** extending from bone hole **52**, first free end **22** is passed through tissue **60** at a first tissue penetration location **62**, second free end **24** is passed through a second tissue penetration location **64**, and the loop-end is passed through a third tissue penetration location **66**. In some embodiments, free ends **22** and **24** may be passed through the same tissue penetration location. Free ends **22** and **24** are passed through loop **26** and continuously tensioned until loop **26** cinches down around free ends **22** and **24**. As loop **26** is cinched, tissue **60** is drawn closer to and compressed against bone **50** surrounding hole **52**.

Free ends **22** and **24** are available to be utilized in conjunction with at least one additional anchor (filamentary or the like), for example, in the formation of a suture bridge. As such, no knots need be formed and continuous tension may be applied to free ends **22** and **24** keeping loop **26** cinched and tissue **60** compressed against bone **50**.

The tissue penetration locations **62**, **64** and **66** can be arranged in any number of configurations and may generally form a triangular pattern as in FIG. **1**D. For example, the first, second and third penetrations **62**, **64**, **66** can be situated to form an equilateral triangle. In another embodiment, an isosceles triangle may be formed in which first and second penetrations **62** and **64** are substantially equally spaced from third penetration **66**. In a further embodiment, penetration **62**, **64**, **66** may be arranged in the form of a right triangle such that first or second penetration is closer to the third penetration **66** than the other penetration. Other triangular configurations may also be utilized. In addition, penetration locations **62**, **64**, **66** may be located all within an area directly above bore hole **52**, or one or more penetration may be located beyond the periphery of bore hole **52**.

In some circumstances, a particular triangular configuration may be chosen to help direct tension applied to the tissue via filament **20**. For example, as depicted in FIG. **1**D, tissue **60** may be a rotator cuff. Third penetration **66**, as depicted, is located medial of first and second penetrations **62** and **64**, which are aligned in a row in an anterior/posterior direction. First and second penetrations **62** and **64** are equally spaced from third penetration **66** to form an isosceles or equilateral triangular pattern. Tension is applied to free ends **22** and **24** in either the lateral or medial direction, which cinches loop **26**. As loop **26** becomes tighter, the resultant tension applied to the rotator cuff **60** is in a direction which substantially bisects first and second penetrations **62**, **64**, which is at least partially due to the symmetrical nature of the depicted triangular configuration. Thus, in the example provided in FIG. **1**E, the rotator cuff **60** would be tensioned in substantially the medial/lateral direction toward the humerus. Free ends may then be directed over apex and fixed to a second and/or third bone anchor **72** that is disposed lateral to sleeve **12**.

In another example, a right-triangular pattern may be formed in which first penetration **62** is closer to third penetration **66**. When free ends **22** and **24** are advanced through loop **26** and tensioned, the resultant tension applied to the rotator cuff may be in both the lateral/medial and anterior/posterior directions.

It should be understood that a triangular configuration comprised of penetrations **62**, **64** and **66** may have alternative orientations from that depicted in FIG. **1**D. For instance, in one embodiment, the triangular pattern shown in FIG. **1**D may be mirrored such that third penetration **66** is located lateral to first and second penetrations **62**, **64**. Alternatively, the triangular pattern may be oriented orthogonally from the depicted location such that third penetration **66** is located more anteriorly or more posteriorly than first and second penetrations **62**, **64**. The specific orientation and positioning of the penetration locations (indeed, the configuration of any of the disclosed devices and methods herein) may be dependent on the type of repair required. For example, for the rotator cuff, such positioning can be dependent on whether the injury is a full thickness, partial thickness, PASTA lesion, trans-tendinous, or the like.

FIG. **2**A depicts an alternative embodiment fixation assembly **100**. Fixation assembly **100** is similar to fixation assembly **10** in that it includes a filamentary sleeve **112** and length of filament **120**, which can be the same as filamentary sleeve **12** and length of filament **20**, respectively. However, fixation assembly **100** differs in that filament **120** is joined at a junction **127** to form a loop **126** that defines a loop-end of filament **120**, an apex **128**, and a crotch **129**. Junction **127** may be formed by a splice, such as a Brummel splice, by braiding filament **120** together at the junction location, by mechanical means, such as a clamp, or by some other means as is known in the art.

FIGS. **2**B-**2**D depict a method of using fixation assembly **100**. The method of using fixation assembly **100** is similar to the method of using fixation assembly **10** in that sleeve **112** is inserted and anchored into a bone hole **152**. Thereafter, first and second free ends **122**, **124** of filament **120** are passed through tissue **160** at first and second tissue penetration locations **162**, **164**, respectively, while the loop-end is passed through a third tissue penetration location **166**. Such penetration locations **162**, **164**, **166** may be arranged in various triangular patterns as previously described.

As shown in FIGS. **2**B-**2**D, at least a portion of loop **126**, and optionally all of the loop **126** and junction **127**, is passed through tissue **160**. In particular, as illustrated, when free ends **122** and **124** are tensioned, loop **126** remains above the tissue without reentering penetration **166**. Junction **127** may be configured such that it collapses over penetration **166** or is otherwise structured so that it cannot be passed back through tissue **160**. For example, junction **127** can have braiding or an additional sleeve/skirt attached to junction

127 that has a narrow profile while passing through tissue 160 in one direction, while collapsing and expanding when there is an attempted advancement back through tissue 160. In another example, a thermoreactive material, such as hydrogel or Nitinol can be applied at the location such that it expands upon the application of heat once passed through tissue 160. Such a configuration may assist in compression of the tissue, at location 166, against underlying bone.

In another embodiment, loop 126 and junction 127 may not completely exit penetration 166 or may be readily passed back into and through penetration 166. Thus, as free ends 122 and 124 are tensioned, a portion of loop 126 is pulled into sleeve 112 as another portion of loop 126 cinches down around free ends 122 and 124 resulting in a configuration that has the appearance of FIG. 1D.

FIG. 3A depicts another fixation assembly embodiment 200. Fixation assembly 200 also includes a filamentary sleeve 212 and length of filament 220. Sleeve 212 may be the same as filamentary sleeve 12. Filament 220 may be similar to filament 120 such that filament 220 includes a junction forming a loop 226 that defines a loop-end of filament 220, a crotch 229 and an apex 228. Filament 220 also includes a first free end 222 and a second free end 224 that each extend from the junction. In some embodiments, first free end 222 may have a shorter length than second free end 224, a longer length than free end 224 or the same length as free end 224, but, regardless, both may have a length sufficient to be used in conjunction with an arthroscopic cannula. When sleeve 212 and filament 220 are assembled, second free end 224 passes through the passageway of sleeve 212 and out of the second end 216, while loop 226 and first free end 222 extend from the first end 214 of sleeve 212.

FIGS. 3B-3E depict one exemplary method embodiment of using fixation assembly 200. As shown in FIGS. 3B and 3C, a bone hole 252 is formed in bone 250, and filamentary sleeve 212 is inserted and anchored into bone hole 252. First free end 222 and loop 226 are passed through a first tissue penetration location 262, and second free end is passed through a second tissue penetration location 264. Thereafter, second free end 224 is advanced through loop 226 and tensioned. First free end 222 may also be tensioned simultaneously with the second free end 224 to help tension the structure and to help prohibit loop 226 and first free end 222 from being drawn through second penetration 262 during tensioning of second free end 264. As tension is applied, filament 220 compresses tissue 260 against bone 250.

As shown in FIGS. 3D and 3E, tissue 260 may be a rotator cuff, and first and second penetrations 262, 264 may be aligned in an anterior/posterior direction. Second free end 224 extends from loop 226 at apex 228, first free end 222 extends from junction 227, and loop 226 extends along tissue 260 between first and second penetrations 262, 264. Thereafter, first and second free ends 222, 224 may be secured laterally to bone 250 via bone anchors 272 and 274, respectively. Bone anchors 272 and 274 may each be a filamentary anchor, such as sleeve 12, or a solid anchor as is known in the art. Alternatively, both the first and second free ends 222, 224 may be secured laterally to bone 250 via a single bone anchor (not shown). Therefore, as described, a surgical knot need not be applied.

FIG. 4A illustrates another fixation assembly embodiment, fixation assembly 300. Fixation assembly 300 includes a filamentary sleeve 312 and a length of filament 320. Filamentary sleeve 312 may be the same as sleeve 12.

Filament 320 includes a first end 321, a second end 325, and a tape portion 323 disposed between first and second ends 321, 325. First and second ends 321, 325 are joined to tape portion 323 either by being braided together as a single construct or are coupled by other means such as gluing, sewing, or welding together, for example. First end 321 of filament 320 includes a loop 326. Loop 326 may be formed as previously described, for example, by splicing filament 320 at junction 327 to form loop 326.

Tape portion 323 has a generally flat cross-section that includes a height (h) and width (w), as shown in FIG. 4B. First and second ends 321, 325 preferably include a rounded cross-sectional profile having a diameter. Thus, as shown, filament 320 may have a round-flat-round configuration. The width of the tape portion 323 is preferably greater than the diameter of the first and second ends 321, 325, while the height of the tape portion 323 may be substantially equal to or less than the diameter of ends 321 and 325.

In one embodiment, filament 320 may have a round-flat configuration in which filament 320 would only be comprised of end 321 and flat portion 323. In such an embodiment, end 321 would form loop 326. In another embodiment, filament 320 may have a flat-round configuration in which filament 320 would only be comprised of flat portion 323 and end 325. In this embodiment, tape portion 323 would form loop 326. In a further embodiment, filament 320 may be flat along its entire length. In other words, in this example filament 320 may be comprised entirely of tape portion 323 with no rounded portions/ends. In yet another embodiment, first and second ends 322, 323 may have a rectangular cross-sectional profile in which the width of tape portion 323 may be greater than the width of the ends 321 and 325, and the height of the tape portion may be substantially equal to or less than the height of the tape portion. The flat profile and relatively large width of the tape portion may facilitate a broad compressive footprint and help reduce irritation of the tissue. Such filaments may have any configuration of round and/or flat portions as desired.

When assembled, sleeve 312 is preferably arranged about first end 321 such that first end 321 is at least partially disposed within the passageway of sleeve 312. In the embodiment shown in FIG. 4A, or other embodiments, such as a flat-round embodiment or entirely flat embodiment, sleeve 312 may be alternatively arranged about tape portion 323.

FIGS. 4C-4E depict an exemplary method of using fixation device 300. A bone hole 352 is formed in bone 350, and sleeve 312, which is slidably attached to first end 321, is inserted into bone hole 352, as shown in FIG. 4C. First and second ends 321, 325 are tensioned to seat sleeve 312 into an anchoring position. Loop 326 is at least partially passed through a first tissue penetration location 362, and second end 325 and tape portion 323 are passed through a second tissue penetration location 364. Second end 325 and tape portion 323 are advanced through the loop 326 such that loop 326 encompasses a portion of first end 321.

In an example of a rotator cuff, as illustrated in FIGS. 4D and 4E, second end 325 is tensioned and tape portion 323 is extended over tissue 360. Second end 325 is then attached to a bone anchor (filamentary or the like) and secured to bone 350. In this manner, tape portion 323 forms a broad compressive footprint to facilitate tissue adhesion to bone 350.

FIG. 5A depicts a further fixation assembly embodiment, fixation assembly 400. Fixation assembly 400 includes a filamentary sleeve 412 and a length of filament 420. Filamentary sleeve 412 may be the same as sleeve 12.

Filament 420 is divided into a first segment 420*a* and a second segment 420*b* each having a distinctive braiding

pattern. For example, first segment may have spiral braiding pattern **428**, and second segment may have a speckled braiding pattern **429**, as shown in FIG. **5**B. However, it should be understood that filament **420** can have the same braiding pattern throughout, or a pattern along only one segment or along a portion of one or both segments, or the like.

The braiding pattern or patterns may be formed in any manner desired. For example, one or more fibers of a distinct color may be woven into the braid (as in FIG. **5**B) to create a desired pattern along a portion, segment or the entirety of the filament. In another example, a surgical marker or pen may be used to mark a portion, segment or the entirety of the filament with a particular pattern, color or the like. For instance, a blue pen could be used to designate segment **420***a* while a red pen could be used to designate segment **420***b*. Such pattern or color differences can assist a surgeon in keeping track of the filament lengths during the surgical procedure.

Filament **420** includes a first end portion **422**, a second end portion **424**, an intermediate portion **421**, a first tape portion **423**, and a second tape portion **425**. First tape portion **423** is disposed between first end **422** and intermediate portion **421**, and the second tape portion **425** is disposed between the second end **424** and intermediate portion **421**. A loop **426** is formed by intermediate portion **421**, for example, by splicing filament **420** at a junction **427**.

First segment **420***a* comprises loop **426**, first end **422**, first tape portion **423**, and a length of intermediate portion **421** that extends from the junction **427** to the first tape portion **423**. Second segment **420***b* comprises second end **424**, second tape portion **425**, and a length of intermediate portion **421** that extends from junction **427** to second tape portion **425**.

Tape portions **423** and **425** are similar to tape portion **323**. First end **422**, second end **424**, and intermediate portion **421** are similar to ends **321** and **325**. Thus, filament **420** preferably has a round-flat-round-flat-round configuration. In other embodiments, filament **400** may have configurations as described with respect to filament **320**. For example, filament **400** may have a round-flat-round, round-flat, flat-round, rectangular-flat-rectangular, entirely flat, or any other configuration as desired.

In addition, tape portions **423** and **425** may be joined to intermediate portion **421** and end portions **422** and **424** by being braided together as a single construct or coupled by other means such as gluing, sewing, or welding together, for example. First and second ends **422**, **424** and intermediate portion **421** also have a corresponding height and width, or, alternatively, a diameter. The width of tape portions **423** and **425** are greater than the width/diameter of first and second ends **422**, **424** and intermediate portion **421**. When applied to tissue, tape portions **423** and **425** generally extend over soft tissue and compress the tissue against bone. The flat profile and relatively large width may facilitate a broad compressive footprint and may help reduce irritation of the tissue.

Sleeve **412** can be assembled with filament **420** in a similar fashion to fixation assembly **200**, shown in FIG. **3**A. For example, sleeve **412** may be positioned about a length of the intermediate portion **421** that extends between junction **427** and second tape portion **425**, or, alternatively, between junction **427** and first tape portion **423**. In some embodiments, depending on the configuration of filament **400**, sleeve **412** may be positioned about tape portion **422** or **424**.

FIGS. **5**C-**5**E depict one exemplary method of using fixation assembly **400**, which is similar to the method of using fixation device **200**, as shown in FIGS. **3**B-**3**E. In this method, a bone hole **452** may be formed in bone **450** and sleeve **412** inserted into the bone hole **450**, as shown in FIG. **5**C. First end **422**, first tape portion **423** and loop **426** are passed through a first tissue penetration location **462**, and second end **424** and second tape portion **425** are passed through a second tissue penetration location **464**. Second end **424** and second tape portion **425** are then passed through loop **426** and second end **424** and optionally first end **422** are tensioned.

In an example of a rotator cuff repair, such as a partial thickness tear, as illustrated in FIGS. **5**D and **5**E, first and second ends **422**, **424** are tensioned in a medial/lateral direction. First end **422** and first tape portion **423** are advanced over tissue **460** and anchored to bone **450** with the bone anchor **472**. Second end **424** and second tape portion **425** are also advanced over tissue **460** and anchored to bone **450** with bone anchor **474**. In this manner, tape portions **423** and **425** may form a broad compressive footprint to facilitate tissue adhesion to bone **450**. In an alternative embodiment, both first and second ends **422**, **424** may be secured laterally to bone **450** via a single bone anchor (not shown).

Alternative configurations of filament **420** and sleeve **412** and methods of using same are envisioned. For example, filament **420** and sleeve **412** can be assembled and used in a similar fashion as fixation device **100**, shown in FIG. **2**A.

FIG. **6**A depicts yet another fixation assembly embodiment **500**. Fixation assembly **500** generally includes a first length of filament **520**, a second length of filament **530** and three filamentary sleeves **512***a-c*. However, it should be understood that fixation assembly **500** can include any number of filamentary sleeves **512**, such as one, two, three or four filamentary sleeves, for example. It should also be understood that any number of filaments may be utilized in fixation assembly **500**, such as one, two, three, or four filaments, for example. Each of sleeves **512***a-c* may be the same as sleeve **12**, described above. In addition, each length of filament **520**, **530** may be the same as filament **20**.

Continuing with the illustrated exemplary embodiment, once assembled, filaments **520** and **530** extend through each sleeve **512***a-c* such that first free ends **522** and **532** extend from third sleeve **512***c* and second free ends **524** and **534** extend from second sleeve **512***b*. In some embodiments, a single length of filament may be assembled with sleeves **512***a-c* in the same manner as filaments **20**, **120**, and **220** as shown in FIGS. **1**A, **2**A, and **3**A.

FIG. **6**B depicts one embodiment of an inserter device **600**, which can be implemented with fixation assembly **500**. Inserter **600** generally includes a body **610**, a head connector **612**, retaining arms **614**, and three removable heads **620***a-c*. However, it should be understood that any number of removable heads **620** may be utilized, which may largely depend on the number of sleeves **512** being implanted. For example, inserter device **600** may include one, two, three, or four removable heads **620**.

Removable heads **620***a-c* each generally include a connector portion **622**, an elongate shaft **624**, and an insertion tip **626** having a retaining slot **628**. Elongate shaft **624** may be sufficiently long to be implemented through an arthroscopic cannula. Each head **620** is capable of being attached and detached to the connector **612** via a quick-connect mechanism, which may include magnets, a ball detent, or the like. Insertion tip **626** may be sharpened to penetrate tissue and insert sleeve **512** into a preformed bone hole. In other embodiments, penetration end **626** may be

sharpened to penetrate bone and tissue in the manner of a punch. Retaining slot **628** is configured to releasably hold sleeve **512** in a bent configuration while filaments **520** and **530** are slidably retained by each sleeve **512***a-c*. Optionally, an actuating arm or arms (not shown) can cover slot **628** during penetration of tissue and can be actuated so that it is moved out of the way during implantation of sleeve into bone. Retaining members **614** are attached to body **610** and configured to hold any of the removable heads **620***a-c*.

Inserter **600** and fixation assembly **500** may be preassembled, packaged, and delivered to the operating theater. Alternatively, inserter **600** and fixation assembly **500** may be packaged and delivered unassembled to the operating theater where assembly takes place. When assembled for use, first removable head **620***a* is attached to connector **612** and second and third removable heads **620***b*, **620***c* are retained by retaining members **614**. Each head **620***a-c* includes a respective sleeve **512** located in respective slots **628** and each filament **520**, **530** is disposed within each sleeve **512***a-c* such that first free ends **522** and **532** and second free ends **524** and **534** extend from removable heads **620***c* and **620***b*, respectively. Filaments **520** and **530** are slidable within sleeves **512***a-c* so that they may be tensioned during implantation of sleeves **512***a-c* as needed.

FIGS. **6**C-**6**E depict one exemplary embodiment of a method of using inserter device **600** and fixation assembly **500**. In this method, each sleeve **512***a-c* is generally inserted through tissue **560** and implanted into bone **550**. However, it is envisioned that each sleeve **512***a-c* may be implanted into bone **550** and then a single length of filament having a loop may be passed through tissue **560** in a similar manner as that described with respect to FIGS. **1**A-**5**E.

Prior to implantation, three bone holes **552***a-c*, one for each sleeve **512***a-c*, may be formed in bone **550** at desired locations. For example, in a rotator cuff reparation procedure, bone holes **552***a-c* may be formed in a medial row generally aligned in an anterior/posterior direction. Tissue **560** may then be tensioned and first head **620***a* containing first sleeve **512***a* is inserted through tissue **560** at first tissue penetration location **562***a*. Thereafter, insertion tip **626** and sleeve **512***a* are inserted into the first bone hole **552***a*, sleeve **512***a* is released therein, and head **620***a* is removed from the bone hole **552***a*. Filaments **520** and **530**, which extend from first bone hole **552***a*, first penetration **562***a*, and through sleeves **512***b* and **512***c*, are tensioned to fully seat sleeve **512***a*.

Thereafter, first head **620***a* is detached from connector **612** and second head **620***b* retaining second sleeve **512***b* is attached to connector **612**. Second head **620***b* is then inserted through tissue **560** at a second tissue penetration location **562***b*. Second sleeve **512***b* is inserted into second bone hole **552***b* and released therein. Second head **620***b* is removed from second bone hole **552***b* and second free ends **524** and **534** along with a portion of filaments **520** and **530** that extend between the first and second sleeves **512***a*, **512***b* are tensioned to fully seat sleeve **512***b*.

Thereafter, second head **620***b* is detached from connector **612** and third head **620***c* retaining third sleeve **512***c* is attached to connector **612**. Third head **620***c* is then inserted through tissue **560** at a third tissue penetration location **562***c*. Third sleeve **512***c* is inserted into third bone hole **552***c* and released therein. Third head **620***c* is removed from third bone hole **552***c* and first free ends **522** and **532** along with a portion of filaments **520** and **530** that extend between the first and third sleeves **512***a*, **512***c* are tensioned to fully seat third sleeve **512***c*.

The operator retains control of first free ends **522** and **532** and second free ends **524** and **534**. As illustrated in FIGS. **6**D and **6**E, these ends are then tensioned which cinches down the portions of filaments **520** and **530** that extend between each sleeve **512***a-c*. As this occurs, tissue **560** underlying these portions of filaments **520** and **530** is compressed against the underlying bone. The free ends **522**, **524**, **532**, **534** are available to be attached to one or more bone anchors, filamentary or the like. For example, in a rotator cuff repair and as shown in FIG. **6**E, first free end **522** and second free end **524** may be anchored via anchors **572** and **574**, respectively, to the humerus beyond the lateral edge **568** of the tissue **560**. Additionally, first free end **532** and second free end **534** may be anchored to the humerus through tissue **560** via anchor **576**, as shown. While FIGS. **6**D and **6**E illustrate one example, other configurations may be formed dependent on the type of soft tissue, type of repair, number of filaments, and number of bone anchors.

FIG. **7** depicts an alternative inserter device **700**, which may be utilized in conjunction with fixation assembly **500**. Inserter device **700** is similar to inserter device **600** in that it includes a body **710** and a plurality of heads **720**. In addition, each head **720** releasably retains a filamentary sleeve **512** while at least one filament extends through each sleeve. However, unlike inserter **600**, each head **720** is attached to body **710** in a configuration for substantially simultaneous insertion of sleeves **512***a-c*. Thus, during operation, each head **512***a-c* concurrently punctures through tissue **560** and is advanced into their respective bone holes where sleeves **512***a-c* are deposited and anchored. It is envisioned that the body **710** could be adjusted, or otherwise, to adjust the spacing of the heads **720**.

FIGS. **8**A-**8**D depicts another inserter device embodiment **800**. Inserter **800** generally includes an intermediate shaft **802**, a first insertion end **810** disposed at one end of intermediate shaft **802**, and a second insertion end **820** disposed at another end of intermediate shaft **802**. Inserter **800** can be made of any biocompatible material, such as stainless steel or titanium.

Intermediate shaft **802** is elongate and may include a connection feature, such as through-hole **804**, at a location along its length. Through-hole **804** may be dimensioned to receive a retaining mechanism, such as a retaining pin, for retaining externally connected devices, such as a suture cleat **840** (depicted in FIG. **10**A), to intermediate shaft **802**. Other retaining mechanisms and connecting features are also envisioned.

As illustrated in FIGS. **8**C and **8**D, first insertion end **810** generally includes an insertion shaft **816** and prongs **812** disposed at a terminal end of insertion shaft **816**. Prongs **812** each have a penetrating tip **811**, which may be sufficiently sharp to penetrate or pierce soft tissue. Penetrating tip **811** may also be sufficiently sharp and prongs **812** sufficiently rigid to penetrate cortical and/or cancellous bone. As shown, prongs **812** taper in at least two planes, which may provide rigidity and facilitate ease of penetration. However, it should be understood that the other tip configurations are envisioned. For example, prongs **812** may each have a dull tip, which can be used when a preformed hole in bone is provided. Alternatively, the tip may include a single prong or have a different feature for engaging or manipulating tissue.

Continuing with this embodiment, prongs **812** also define a recess **814** therebetween. Recess **814** defines a crotch **813** and is dimensioned to receive and retain a first anchor (not shown), such as a filamentary sleeve anchor **12**. More particularly, recess **813** is dimensioned such that the first anchor can be placed in recess **814** and bent over crotch **813**

so that the first anchor sits below penetrating tips **811**. Another example of a filamentary sleeve anchor can include the Iconix® all-suture suture anchor system (Stryker Corporation, Kalamazoo, Mich.). Other examples of filamentary sleeve anchors that may be used in conjunction with inserter **800** are described in the heretofore referenced applications and patents incorporated by reference herein.

Insertion shaft **816** is dimensioned to fit within a bone hole of predetermined size. In addition, insertion shaft **816** has a length corresponding to a desired depth of the bone hole. Insertion shaft **816** has two indented surfaces **818** disposed on opposite sides thereof. Such indented surfaces **818** intersect recess **814**. This allows for a filamentary sleeve anchor **12** to be folded over crotch **813** and for opposing ends of the sleeve anchor to extend along indented surfaces **818**. Indented surfaces **818** help provide clearance space for the sleeve anchor so that, for example, when the sleeve anchor is coupled to first insertion end **810**, first insertion end **810** and the anchor sleeve together have a more narrow width than without indented surfaces **818**. Thus, together these can fit within a more narrow bone hole. In other words, indented surfaces **818** provide for a smaller profile of the inserter and anchor thereby allowing for a smaller bone hole. Indented surfaces **818** may be planar or may be concavely grooved, which may provide rigidity to insertion shaft **816** at this location.

A shoulder/collar **806** is disposed between intermediate shaft **802** and insertion shaft **816**. Shoulder/collar **806** can generally include an abutment surface **807**, a transverse through-hole **808** and longitudinally extending slots **809**. Shoulder/collar **806** has a maximum cross-sectional dimension larger than a cross-sectional dimension of insertion shaft **816**. As such, abutment surface **807** serves as a depth stop indicating to an operator when the appropriate insertion depth of insertion end **810** has been reached. Also, abutment surface **807** acts as an impact surface for a removable cap, as described in more detail below.

Transverse through-hole **808**, if present, extends through the shoulder/collar **806** and is dimensioned to receive at least one filament therein. However, through-hole **808** can accommodate more than one filament. Longitudinally extending notches **809**, if present, intersect transverse through-hole **808**. Such notches **809** are formed to provide a gap for one or more filaments when a removable cap is connected to first insertion end **810**, as described further below.

Second insertion end **820** is identical to first insertion end **810**. In addition, a second shoulder/collar is disposed between intermediate shaft **802** and second insertion shaft **816** and is identical to first shoulder/collar **806** described above. Although, second insertion end **820** is preferably identical to first insertion end **810**, it is contemplated that other embodiments of inserter **800** may include a second insertion end adapted for other anchor types. For example, first insertion end **810** may be configured to retain a filamentary sleeve anchor as described above, and second insertion end **820** may be configured to retain a hard anchor, in a manner known in the art. Even further, first and second insertion ends **810**, **820** may each be configured to retain a hard anchor.

FIG. **9** depicts one embodiment of a cap **830**, which may be used in conjunction with inserter **800**. Cap **830** is generally cylindrical and includes a planar impact surface **832** and a planar abutment surface **838** (see FIG. **10**C) disposed at opposite ends of cap **830**. A bore **834** extends through abutment surface **838** and into cap **830**. As shown, bore **834** is a blind bore and, therefore, does not extend all the way through cap **830**. However, in some embodiments, bore **834** can extend through the entirety of cap **830**. Bore **834** is dimensioned to be longer than first and second insertion ends **810**, **820**. Bore **834** is also dimensioned to receive each of insertion ends **810**, **820** therein, even when their respective bone anchors are retained thereon. Cap **830** may also include longitudinally extending grooves **836**, which can be used as filamentary pathways to facilitate suture/filament management.

FIGS. **10**A-**10**C depict cap **830** assembled to the inserter **800** in an exemplary embodiment. In the assembly, first insertion end **810** extends into bore **834** and abutment surface **838** of cap **830** abuts abutment surface **807** of shoulder/collar **806**. Such abutment surfaces **807**, **838** may lie flush against each other to facilitate uniform impact distribution. Although insertion end **810** is depicted without a bone anchor, as mentioned above, cap **830** is capable of fitting over first insertion end **810** with a first bone anchor attached thereto.

Also, as best shown in FIG. **10**B, when first insertion end **810** is disposed within bore **834**, a space may exist between prongs **812** and an end of bore **834**. This prevents prongs **812** from being damaged during impaction, as discussed further below.

Moreover, as best shown in FIG. **10**C, when the respective abutment surfaces **807**, **838** contact each other, a gap **833** may be formed by the longitudinally extending notches thereby exposing bore **834**. Such gap **833** is sized to allow for one or more filaments to extend therethrough.

In one embodiment of a method of using inserter **800** and cap **830**, inserter **800** may be provided preassembled with first and second filamentary bone anchors (not shown). In such a preassembled configuration, the first anchor may be disposed within recess **814** and bent over crotch **813** such that a first and second ends of the filamentary anchors extends along respective indented surfaces **818**. The second bone anchor may be similarly situated on second insertion end **820**. One or more filaments preferably connects to the first and second anchors such that the anchors are coupled to each other by the one or more filaments and such that a first end of the one or more filaments extends from the first anchor and a second end extends from the second anchor. Such anchor and filament arrangement may be similar to that shown in FIG. **6**B. In addition, the one or more filaments can include one or more tape portions, such as with filaments **320** and **420** described above. Also, the one or more filaments can form adjustable or fixed loops, such that in assemblies **10**, **100**, **200**, **300** and **400**.

First insertion end **810** along with the first anchor are passed through an arthroscopic cannula (or incised tissue in open surgery). Penetrating tips **811** may then pierce through soft tissue, such as a rotator cuff, and be placed adjacent to bone (e.g., in a PASTA repair). When the desired location for anchor placement is determined, the operator impacts impact surface **832** of cap **830**, which is extracorporeally located and disposed over second insertion end **820** and the second bone anchor. The force of the impacts is transferred from cap **830** to inserter **800** via the shoulder/collar **806**. The operator continues to impact cap **830** until abutment surface **807** of shoulder/collar **806** contacts the bone and provides resistance to the operator indicating that the appropriate depth has been reached. In one embodiment, impaction of cap **830** penetrates bone without the use of a preformed hole. As such, penetrating tips **811** and the two-plane taper of penetrating tips **811** helps facilitate penetration. In an alternative embodiment, a preformed hole is provided, and impaction helps advance first insertion end **810** and the first

bone anchor into the preformed hole. In the variation where the inserter is a self-tapping inserter, the crotch and recesses **814** and indented surfaces **818** may protect the implant from damage from contact with the bone.

With first insertion end **810** and the first anchor fully inserted into a bone hole, the operator removes first insertion end **810** from the bone hole. The tight fit and friction of the bone helps the first anchor slide through recess **814** and remain in the bone as first insertion end **810** is removed. The one or more filaments extending from the anchor are tensioned to expand and fully seat the first filamentary sleeve anchor. Slack in the one or more filaments may be provided as needed.

First insertion end **810** is removed from the patient via the arthroscopic cannula. Cap **830** is removed from second insertion end **820** and the second bone anchor and placed over first insertion end **810**. Second insertion end **820** and the second bone anchor are passed through the arthroscopic cannula. Soft tissue is penetrated by second insertion end **820**, and impact surface **832** of the cap **830** is impacted in the same manner as when implanting the first anchor. Once second insertion end **820** and the second bone anchor are fully inserted into bone, second insertion end **820** is removed while the second bone anchor remains within the bone hole. The one or more filaments are tensioned to fully seat the anchor. The resulting anchor and filament arrangement may be similar to that shown in FIGS. **6**C and **6**D, with the exception that the tissue is anchored by two anchors rather than three.

Although inserter **800** is described in conjunction with cap **830** for its use, it should be understood that in some embodiments, inserter **800** may be used without a cap. For example, prongs **812** may have a dull flat surface and be used to insert filamentary sleeves in preformed bone holes. A mallet may be used to strike the end of such prongs to assist in inserting the anchors into the bone holes.

Inserter **800** provides significant benefits, which includes a construction that allows for preassembly of two bone anchors with filaments. This facilitates quick implantation of the bone anchors and ease of use, particularly by reducing suture management responsibilities of the operator.

Although it has been described that the first and second insertion ends penetrate soft tissue prior to impaction into bone, it should be understood that inserter **800** can be used to implant anchors and filaments under tissue without penetrating such tissue.

In still other embodiments, insertion devices such as those discussed above can be used with alternative suture and/or suture anchor structures. Such alternative structures, some of which are described above, may be useful in certain surgical methods and techniques.

FIGS. **11**A-**14** depict an inserter assembly **1010** according to another embodiment of the present disclosure. Inserter assembly **1010** generally includes a handle **1020**, first inserter **1030**, second inserter **1050**, cap **1040**, and sleeve **1060**.

The handle **1020** includes a handle body **1029** which defines a passageway that extends entirely through the body **1029** in a proximal-distal direction. The cross-sectional dimension of the passageway generally increases in the distal direction which forms at least two distally facing surfaces **1021** and **1023**, as best shown in FIG. **12**C. A longitudinal slot **1025** extending through a proximal end of the handle body **1029** intersects the passageway along a portion of the length of the handle body **1029**, as best shown in FIG. **13**B, so as to receive a pin **1036** that extends from the first inserter **1030**. An engagement feature **1024** is disposed within the handle **1020** adjacent the passageway so as to interface with the sleeve **1060** when disposed in the passageway (see FIG. **12**C). As shown in the depicted embodiment, the engagement feature **1024** is a ball assembly of a ball-detent mechanism. However, the engagement feature **1024** can be a user actuated pin or some other feature known in the art for selectively retaining a moving component.

The handle body **1029** also defines exterior features. For example, one or more suture cleats **1022** (see FIG. **12**B) are disposed on an outer surface between the proximal and distal ends of the handle body **1029**. These cleats **1022** are configured to temporarily retain a suture/filament which may pass through bone anchors mounted to the inserters **1030**, **1050**, as described below. The handle body **1029** also includes a proximal impact surface **1028** which may be impacted when the cap **1040** is not connected to handle body **1029**. A socket **1026** may extend distally into the impact surface **1028** and may have a non-circular geometry to match a distal projection **1044** of the cap **1040** while prohibiting the cap **1040** from rotating therein, as shown in FIG. **12**A. The handle body **1029** also includes grooves **1027** at the proximal end that can be engaged by the cap **1040**, such as by engagement members **1042**, to temporarily lock the cap **1040** to the handle body **1029**. Wings (not shown) may extend from the sides of handle body **1029** to provide further grip to the user and to provide additional cleats or filament retaining structures.

The first inserter or removable inserter **1030** is defined by an elongate shaft. An insertion end **1031** is located at a distal end of the elongate shaft, as best shown in FIGS. **11**B and **11**C. The insertion end **1031** includes prongs or penetrating tips **1032** that are separated by a recess **1034**. The penetrating tips **1032** are sufficiently sharp to penetrate or pierce soft tissue. Penetrating tips **1032** may also be sufficiently sharp and sufficiently rigid to penetrate cortical and/or cancellous bone. As shown, tips **1032** taper in at least two planes, which may provide rigidity and facilitate ease of penetration. However, it should be understood that other tip configurations are envisioned. For example, tips **1032** may each have a dull end, which can be used when a preformed hole in bone is provided. Alternatively, the insertion end **1031** may include a single penetrating tip or have a different feature for engaging or manipulating tissue.

Recess **1034** defines a crotch **1037** and is dimensioned to receive and retain a first anchor, such as filamentary sleeve anchor **12**. More particularly, recess **1034** is dimensioned such that the first anchor can be placed in recess **1034** and bent over the crotch **1037** so that the first anchor sits proximal relative to penetrating tips **1034**. Another example of a filamentary sleeve anchor can include the Iconix® all-suture suture anchor system (Stryker Corporation, Kalamazoo, Mich.). Other examples of filamentary sleeve anchors that may be used in conjunction with inserter **1030** are described in the heretofore referenced applications and patents incorporated by reference herein. Also, it should be understood that while insertion end **1031** is particularly configured to retain a soft, filamentary anchor, it is contemplated that the insertion end may be configured to retain a hard anchor as known in the art.

Insertion end **1031** also has two indented surfaces **1033** disposed on opposite sides thereof. Such indented surfaces intersect recess **1037**. This allows for a filamentary sleeve anchor to be folded over crotch **1037** and for opposing ends of the sleeve anchor to extend along indented surfaces **1033**. Indented surfaces **1033** help provide clearance space for the sleeve anchor so that, for example, when the sleeve anchor

is coupled to first insertion end **1031**, first insertion **1031** end and the anchor sleeve together have a narrower width than without indented surfaces **1033**. Thus, together these can fit within a narrower bone hole. In other words, indented surfaces **1033** provide for a smaller profile of the inserter **1030** and anchor thereby allowing for a smaller bone hole. Indented surfaces **1033** may be planar or may be concavely grooved, which may provide rigidity to inserter **1030** at this location.

The cap **1040** is secured to the proximal end of inserter **1030**. The cap **1040** may include a distal projection **1044** configured to be received by the socket **1026** of handle body **1029**. In addition, cap **1040** includes one or more engagement members **1042** that can engage handle body **1029** to temporarily secure cap **1040** to the handle body **1029**. In the depicted embodiment such engagement members **1042** are in the form of flexible fingers that project distally and are capable of snapping into grooves **1027**.

A coupling pin **1036** extends from the first inserter **1030** in a direction transverse to a longitudinal axis of inserter **1030**. Pin **1036** is disposed between cap **1040** and insertion end **1031** and is located closer to cap **1040** than the insertion end **1031**. Coupling pin **1036** helps prevent inserter **1030** from rotating when disposed within handle body **1029** and also helps secure inserter **1030** to sleeve **1060**, as described below.

The second inserter or fixed inserter **1050** is similar to first inserter **1030** in that it is defined by an elongate shaft with a distal insertion end **1051** that is configured to retain a filamentary sleeve anchor, such as anchor **12**. However, second inserter **1050** differs from first inserter **1030** in that second inserter **1050** has a shorter length than first inserter **1030**. In addition second inserter **1050** does not include a coupling pin or cap.

The sleeve **1060** defines a passageway extending therethrough in the proximal-distal direction and is sized to receive first and second inserters **1030**, **1050**, as best shown in FIGS. **12**A and **12**B. Sleeve **1060** includes a cylindrical portion **1067** and semicylindrical portion **1068** projecting proximally from the cylindrical portion **1067** (best shown in FIG. **12**C). However, such portions **1067**, **1068** may have other shapes, such as ovular or rectangular geometries, than cylindrical geometries. Such configuration helps sleeve **1060** conform to the change in cross-sectional dimension of the passageway of the handle body **1029**. A transverse opening **1064** extends through opposite sides of the sleeve **1060** at the distal end thereof. This opening **1064** generally aligns with the insertion end **1051** of the second inserter **1050** when the second inserter **1050** is disposed within the sleeve **1060** and helps provide relief for a bone anchor connected to second insertion end **1051**. In addition, when an anchor is mounted to second insertion end **1051**, a filament may extend through the anchor. Transverse opening **1064** provides a passageway through which such filament can extend. In this regard, the filament would extend through transverse opening **1064** at both sides of sleeve **1060** and extend along the length of sleeve **1060** toward handle **1020**. However, it should be noted that in some embodiments the filament can extend through sleeve **1060** rather than outside of sleeve **1060**.

A notch **1069** extends into the proximal end of the sleeve **1060**. Notch **1069**, as shown in FIG. **11**E, is key-hole shaped and is sized to receive the coupling pin **1036** in an interference fit manner so that the pin and slot connection releasably connects sleeve **1060** to inserter **1030**. In this regard, the interference fit provides a secure connection between first inserter **1030** and sleeve **1060**, but when sufficient force is provided, pin **1036** can be released from notch **1069** in a proximal direction thereby disconnecting sleeve **1060** from first inserter **1030**.

When assembled, the inserter assembly **1010** generally has a first insertion configuration and a second insertion configuration. Assembly **1010** goes through a transition phase which is characterized by multiple stages when transitioning between the first and second configurations, as is described below.

In the first insertion configuration, as depicted in FIGS. **11**A-**11**E, assembly **1010** is configured to implant a first anchor which is mounted to the first insertion end **1031** of first inserter **1030**. In this regard, sleeve **1060** is slidably disposed within the passageway of handle body **1029**, and first and second inserters **1030**, **1050** extend through the passageway of handle body **1029** and also through the passageway of sleeve **1060** so that sleeve **1060** surrounds respective portions of inserters **1030** and **1050**. First inserter **1030** is connected to cap **1040** which is removably connected to the proximal end of handle body **1029**, as shown in FIG. **11**A. Coupling pin **1036** is attached to notch **1069** of sleeve **1060**, and ball assembly **1024** does not engage detent **1066**, but rather slidably contacts an outer surface of sleeve **1060**, as depicted in FIG. **11**D. The connection of cap **1040** to handle **1020** and the pin **1036** to the notch **1069** helps constrain the sleeve **1060** and first inserter **1030** from movement within and relative to handle body **1029**.

Also in the first insertion configuration, second inserter **1050** is fixedly connected or secured to handle body **1029** which prevents inserter **1050** from moving relative to handle **1020**. In this regard, second inserter **1050** is generally connected to the first distally facing surface **1021**, which helps provide an abutment during impaction, which is illustrated in FIG. **12**C.

In addition, the first insertion end **1031** of first inserter **1030** extends further from the handle body **1029** than second insertion **1051** end of second inserter **1050**. This allows first inserter **1030** to deliver a first anchor into bone without obstruction by second inserter **1050**. In addition, second insertion end **1051** is generally disposed within sleeve **1060** so that a terminal end **1062** of sleeve **1060** is located in a first position which is at about the same position distally as the second insertion end **1051**, if not more distal than second insertion end **1051**. Terminal end **1062** is also positioned more proximal than first insertion **1031** end and is located along the length of first inserter **1030** so as to act as a depth stop during insertion of a first anchor. In other words, in the first configuration of assembly **1010**, terminal end **1062** of sleeve **1060** is spaced a predetermined distance from first insertion end **1031** so that when first inserter **1030** is inserted into bone up to terminal end **1062** of sleeve **1060**, the insertion end **1031** is located at the desired depth in the bone. This may be particularly useful during arthroscopic surgery in which inserters **1030**, **1050** and sleeve **1060** are passed through an arthroscopic cannula and the operator's vision of the same may be obscured. In this regard, abutment of bone with sleeve **1060** may provide tactile feedback to the operator indicating to the operator that the appropriate penetration depth has been achieved. Further, such positioning may also serve to protect the second anchor on second insertion end **1051** during insertion of the first anchor.

When transitioning from the first configuration to the second configuration, assembly **1010** generally goes through three different stages. In the first stage, cap **1040** is disconnected from the proximal end of handle body **1029**. This allows first inserter **1030** to move proximally within and relative to handle body **1029**. Also, in this stage coupling pin

1036 remains connected to sleeve 1060, which allows sleeve 1060 to move proximally in conjunction with first inserter 1030.

In the second stage, as depicted in FIGS. 12A-12C, first inserter 1030 is moved proximally relative to its position in the first configuration. In addition, the sleeve 1060, which remains connected to first inserter 1030, is also moved proximally from its first position to a second position. In the second position, the ball assembly 1024 engages detent 1066 of sleeve 1060. Thus, in the second stage of the transition phase, sleeve 1060 is connected to both the first inserter 1030 and handle body 1029, as best shown in FIG. 12C. Also, as is depicted in FIGS. 12A and 12B, the movement of sleeve 1060 into the second position exposes second insertion end 1051 of second inserter 1050. In this regard, terminal end 1062 of sleeve 1060 in the second position is located along the length of second inserter 1050 and relative to second insertion end 1051 so as to operate as a depth stop when inserting a second bone anchor via second inserter 1050. Thus, sleeve 1060 can be moved from a first position in which sleeve 1060 operates as a depth stop for first inserter 1030 to a second position in which sleeve 1060 operates a depth stop for second inserter 1050.

In the third stage of the transition phase, as depicted in FIGS. 13A and 13B, coupling pin 1036 of first inserter 1030 is disengaged from sleeve 1060 while the sleeve 1060 remains in the second position. This generally occurs when a sufficient force pulling on cap 1040 overcomes the connection between pin 1036 and notch 1069. Sleeve 1060 is prevented from being pulled out of handle body 1029 by the ball-detent engagement mechanism 1024, 1066 and also by the second distal facing surface 1023. As such, pin 1036 slides out of notch 1069 and slides out of longitudinal slot 1025 of handle body 1029, as shown. Thus, in the third stage, sleeve 1060 is releasably connected to the handle body 1029 and constrained in the second position via the engagement mechanism 1024, 1066. Also, first inserter 1030 is freed from sleeve 1060 and is unconstrained so as to be removable from handle 1020.

The third stage of the transition phase leads to the second insertion configuration, which is illustrated in FIG. 14. In the second insertion configuration, inserter assembly 1010 is configured to insert a second anchor into bone. In this regard, first inserter 1030 is completely removed from handle 1020. Cap 1040, which can be used to impact first inserter into bone, is also removed from handle 1020 which allows impact surface 1028 of handle 1020 to be used to impact second inserter 1050 into bone. Sleeve 1060 is connected to handle body 1029 in the second position exposing second insertion end 1051 and whatever anchor is mounted thereto. Terminal end 1062 of the sleeve 1060 is positioned relative to second insertion end 1051 so as to operate as a depth stop.

In a method of use, inserter assembly 1010 is utilized to repair soft tissue, such as a rotator cuff, glenoid labrum, acetabular labrum, meniscus, soft tissue in smaller joints such as in the hand, foot, ankle, or wrist, and the like. In an exemplary method, as is now described, the inserter assembly is utilized to repair a torn rotator cuff. Inserter assembly 1010 may be provided to an operator preloaded with bone anchors, such as filamentary anchor 12. In this regard, inserter assembly may be provided in the first insertion configuration (see FIGS. 11A-11D) with a first anchor mounted on the first insertion end 1031 and a second anchor mounted on the second insertion end 1051. These anchors may be bent over respective crotches of the insertion ends 1031, 1051 so that respective ends of the anchors face a proximal direction toward handle 1020. One or more lengths of filament, such as filament 20, extend through both anchors while the anchors are mounted to their respective inserters 1030, 1050 (see, for example, assembly 610 of FIG. 6B). The one or more filaments may engage the cleats 1022 in order to retain the anchors and filament in the desired configuration.

With assembly 1010 in the first configuration and loaded with two anchors, the operator places the first insertion end 1031 of first inserter 1030 adjacent the tissue to be repaired. This may be performed through an arthroscopic cannula or via open surgery. Once the penetration location is identified, the operator impacts cap 1040 which pierces the soft tissue and penetrates bone. The operator continues to impact cap 1040 until terminal end 1062 of sleeve 1060 abuts the bone/tissue indicating that the appropriate penetration depth has been achieved. The operator may then seat the first anchor within the bone hole formed by first insertion end 1031 by pulling the assembly 1010 proximally and tensioning the filament.

Thereafter, the assembly is transitioned to the second insertion configuration. This may be achieved while the assembly extends through the arthroscopic cannula and placed adjacent the repair site. It should be noted that as this transition occurs, the first anchor, which is secured to the bone, is also connected to the second anchor, which is connected to the second inserter 1050, via the one or more filaments. As described above, assembly 1010 goes through several stages of a transition phase to transition from the first insertion configuration to the second insertion configuration. In this regard, the operator detaches cap 1040 from handle body 1029 and moves first inserter 1030 proximally through handle body 1029. As this occurs, sleeve 1060 also moves proximally which unsheathes second insertion end 1051 and the second anchor mounted thereto.

The operator continues to move first inserter 1030 through handle body 1029 until sleeve abuts distally facing surface 1023 and ball assembly 1024 engages detent 1066 of sleeve 1060, which secures sleeve to handle 1020 (see FIGS. 12A-12C). The operator may then apply sufficient force to first inserter 1030 to disconnect pin 1036 from notch 1069 in a proximal direction (see FIGS. 13A-13B). First inserter 1030 is then removed from the proximal end of assembly 1010. Once first inserter 1030 is completely removed, assembly 1010 is in the second insertion configuration (see FIG. 14). The operator then places second insertion end 1051 adjacent the tissue to be repaired in a location offset from the first anchor. Impact surface 1028 is then impacted so as to penetrate the tissue and underlying bone with second inserter 1050. Impact surface 1028 is impacted until terminal end 1062 of sleeve 1060 abuts the tissue and bone, which may be felt by the operator. The operator then seats the second anchor within the hole formed by second insertion end 1051 by pulling assembly 1010 proximally and tensioning the filament. Thereafter, assembly 1010 may be removed from the patient and the filament may be unsecured from the cleats 1022 for further use. The end result may be similar to the implanted configuration shown in FIGS. 6C and 6D with the difference being that there would be two implanted anchors, rather than the three depicted.

Although assembly 1010 has been described as being particularly suitable for implantation of soft, filamentary anchors, it should be understood that assembly could also operate to implant hard anchors where inserters 1030, 1050 are configured to retain hard anchors. The general operation, including the transition from the first insertion configuration to the second configuration, would remain the same.

In addition, assembly **1010** may be utilized in conjunction with standard filament or filament that has round and flat portions, such as filament **320**, for example. In this regard, assembly **1010** may be preloaded with a first and second anchor and a filament that extends through both anchors. Such filament may have a flat portion, such as tape portion **323**, disposed between the two anchors so that when the anchors are implanted, the flat portion spans the implanted anchors helping to compress the damaged tissue to bone.

FIGS. **15**A-**15**C depict an inserter assembly **1110** according to an even further embodiment of the present disclosure. Assembly **1110** is similar to assembly **1010** in that it includes a first inserter **1130**, second inserter **1150**, handle **1120**, sleeve **1160**, and cap **1140**. Also, similar to assembly **1010**, first inserter **1130** is connected to cap **1140** and is removable from handle **1120**, and second inserter **1150** is fixedly connected to handle **1120**. However, assembly **1110** differs from assembly **1010** with regard to handle **1120** and its filament management features.

Handle **1120** includes wings **1126** that extend outwardly from a distal end thereof. Such wings **1126** include tapered notches **1128** that are configured to retain a filament. In addition, a front side of handle **1120** includes two channels **1121***a-b* extending into an outer surface thereof and also extending in a proximal-distal direction from a distal end of the handle (best shown in FIGS. **15**A and **15**B). These channels **1121***a-b* diverge and turn along a circular route so that they intersect themselves. This forms a first and second cleat or full-circle cleats **1122***a-b* for retaining a portion of a filament.

A rear side of handle **1120** also includes channels **1122***c-d* that extend into an outer surface thereof and extend in a proximal-distal direction from a distal end of the handle **1120**. These channels **1122***c-d* also diverge but do not circle back to intersect themselves. This forms a third and fourth cleat or cantilevered cleats **1122***c-d* for retaining a portion of a filament.

FIGS. **15**A-**15**C also depict a filament and anchor assembly in one embodiment configuration as mounted to assembly **1110**. As shown, a first anchor **1101** is mounted to first inserter **1130**, and a second anchor **1102** is mounted to second inserter **1150**. A single length of filament **1190** extends through both anchors **1101**, **1102**. However, it should be understood that multiple filaments can extend through such anchors in a similar fashion, and is generally preferable. However, one filament is depicted as a visualization aid.

Referring to FIG. **15**C, free ends **1192***a-b* of filament **1190** extend along a rear side of sleeve **1160** and external thereto in a proximal direction. Free ends **1192***a-b* extend through channels **1122***c-d* and turn laterally so as to be hooked by cleats **1122***c-d*. Free ends **1192***a-b* extend toward respective wings **1126** and engage notches **1128** so that they are retained therein (best shown in FIG. **15**B).

At the front side of assembly **1110**, a loop end **1196** of filament extends along sleeve **1160** and external thereto in a proximal direction away from anchors **1101** and **1102**. Loop end **1196** is the portion of filament **1190** that extends between anchors **1101** and **1102**. Adjacent segments **1191***a-b* of loop end **1196** extend through channels **1121***a-b* and wrap around cleats **1122***a-b*. The very end of loop end **1196** projects from handle **1120**. This allows an operator to tug loop end **1196** distally to release loop end **1196** from cleats. In this regard, handle **1120** provides quick and easy release of filament.

FIGS. **16**A and **16**B depict an inserter **1200** according to another embodiment of the present disclosure. Inserter **1200** can be utilized in assembly **1010** as both first and second inserters **1030** and **1050**. Inserter **1200** can also be utilized with assembly **1110** and in the other inserter assemblies described further below. Inserter **1200** is defined by an elongate shaft which has indicia **1220**, such as laser etched indicia, located along its length to help indicate penetration depth of inserter **1200**. An insertion end **1210** is located at a distal end of the elongate shaft. Insertion end **1210** includes prongs or penetrating tips **1214** that are separated by a recess **1216**. Penetrating tips **1214** are sufficiently sharp to penetrate or pierce soft tissue. Penetrating tips **1214** may also be sufficiently sharp and sufficiently rigid to penetrate cortical and/or cancellous bone. As shown, tips **1214** taper in at least two planes and, as such, are defined by one or more tapered surfaces.

Recess **1216** defines a crotch **1217** and is dimensioned to receive and retain a bone anchor, such as filamentary sleeve anchor **12**. More particularly, recess **1216** is dimensioned such the anchor can be placed in recess **1216** and bent over crotch **1217** so that the anchor sits proximal relative to penetrating tips **1214**.

Insertion end **1210** also has two indented surfaces **1212** disposed on opposite sides thereof. Such indented surfaces **1212**, as shown, are planar surfaces that extend distally toward the terminal, distal end of inserter **1200**. In this regard, indented surfaces **1212** intersect recess **1216** and the tapered surfaces of tapered tips **1214**. This is in contrast to inserter end **1031**, as shown in FIGS. **11**B and **11**C, in which indented surfaces **1033** terminate at radially extending projections prior to reaching tips **1032**. Indented surfaces **1212** help reduce the profile of insertion end **1210** so that a relatively small hole may be utilized for implantation of a bone anchor.

FIGS. **17**A and **17**B depict an inserter **1300** according to an addition embodiment of the disclosure. Inserter **1300** is similar to inserter **1200** in that it is defined by an elongate shaft and includes an insertion end **1320** having indented surfaces **1312** and penetrating tips **1314** separated by a recess **1316**. However, inserter **1300** differs from inserter **1200**, in that insertion end **1320** has an I-beam configuration. In this regard, flanges **1318** flank indented surfaces **1312** and extend radially outwardly therefrom. This forms a recessed space between flanges **1318** which can receive a portion of a filamentary anchor, such as anchor **12**. In this regard, flanges **1318** help provide stiffness to penetrating tips **1314** for penetration into bone, while also providing a reduced profile for inserting an anchor into a relatively small bone hole.

FIG. **18** depicts an inserter assembly **1410** in a first insertion configuration according to a further embodiment of the present disclosure. Assembly **1410** is similar to assembly **1010** in that it includes a handle **1420**, a first inserter **1430**, a second inserter **1450**, and a cap **1440**. In addition, as with assembly **1010**, first inserter **1430** is attached to cap **1440** and is removable from handle body **1429**, and second inserter **1450** is fixedly connected to handle body **1429** so that second inserter **1450** is immovable relative to handle body **1429**. However, unlike assembly **1010**, assembly **1410** does not include a sleeve, such as sleeve **1060**, and handle **1420** includes wings **1426**. Wings **1426** are similar to wings **1126** in that they have notches **1428** to assist in filament management.

Although assembly **1410** does not have a sleeve to act as a depth stop as described above in relation to assembly **1010**, inserters **1430** and **1450** each include indicia **1432**, **1452**, respectively, along their length that indicate depth level, which can be observed arthroscopically relative to a bone or

tissue surface. In this regard, in a method of operation, first inserter **1430** with a first anchor mounted thereto is impacted through soft tissue into bone until a surface of the bone or tissue aligns with the indicia **1432**. The first anchor is then seated into an opening formed by first inserter **1430** via tensioning of a filament coupled to the first anchor after the anchor is implanted into the opening and first inserter **1430** is removed from the opening. Thereafter, cap **1440** is disengaged from a proximal end of handle body **1429**, and first inserter **1430** is advanced proximally out of handle body **1429**. After first inserter **1430** is removed from handle body **1429**, assembly **1410** is in a second insertion configuration (not shown) for inserting a second anchor mounted to second inserter **1450**. Second inserter **1450** is then impacted through soft tissue into bone at a location offset from the implanted first anchor until indicia **1452** disposed on second inserter **1450** align with a surface of bone or tissue. The second anchor is then seated within the opening formed by second inserter **1450**.

FIG. **19** depicts an inserter assembly **1510** according to an additional embodiment of the present disclosure. Assembly **1510** is similar to assembly **1010** in that it includes a handle **1520**, first inserter **1530**, second inserter **1550**, cap **1540**, and sleeve **1560**. However, assembly **1510** differs with regard to its sleeve engagement mechanism **1524**, which, as depicted, is a constant force spring. As previously described, assembly **1010** utilizes ball assembly **1024** located in handle **1020** to connect handle **1020** to sleeve **1060**. First inserter **1030**, which connects to sleeve **1060** via pin **1036** and slot **1069**, allows sleeve **1060** to be moved from a first position to a second position where the ball-detent mechanism **1024**, **1066** is actuated to connect handle **1020** to sleeve **1060**.

In contrast, constant force spring **1524** is disposed within a recess **1523** in handle **1520** and includes a free end **1525** that is connected to a proximal end of sleeve **1560**. Constant force spring **1524** applies a constant force on sleeve **1560** in the proximal direction. In a first position, sleeve **1560** is at its distal most extent relative to inserters **1530** and **1550**. In this position, a pin **1536** extending from first inserter **1530** abuts the proximal end of sleeve **1560** which pushes sleeve **1560** against the bias of spring **1524**. Additionally, cap **1540** can be secured to the proximal end of handle body **1520**. When cap **1540** is secured, first inserter **1530** via pin **1536** holds sleeve in the first position in which sleeve **1560** acts as a depth stop for first inserter **1530**.

In a second position, cap **1540** is disengaged from handle body **1520** and first inserter **1530** is removed from handle **1520** which also removes the counterforce to spring **1524**. As such, sleeve **1560** is able to automatically retract into handle body **1520** in the proximal direction and into a second position in which sleeve **1560** acts as a depth stop for second inserter **1550**. A distally facing surface **1523** within handle body **1529** prevents sleeve **1560** from retracting any further beyond the second position.

A method of operation of assembly **1510** is similar to that of assembly **1010**. In this regard, first inserter **1530** is impacted into bone until the bone or tissue contacts sleeve **1560** so as to implant a first anchor. First inserter **1530** is removed from handle **1520**, and sleeve **1560** automatically retracts into its second position where it abuts distally facing surface **1523**. Second inserter **1550** is then impacted into bone until the bone or tissue contacts sleeve **1560** so as to implant a second anchor into the bone.

FIGS. **20**A and **20**B depict an inserter assembly **1610** according to yet another embodiment of the present disclosure. Assembly **1610** includes a handle **1620**, a first inserter **1630**, a second inserter **1650**, a first cap **1640**, a second cap **1670**, a sleeve **1660**, and a pull tab **1680**. First inserter **1630** is connected to first cap **1640** at its proximal end. Second inserter **1650** is connected to second cap **1670** at its proximal end. Similar to assembly **1010**, first inserter **1630** is longer than second inserter **1650**, and first inserter **1630** is removable from handle body **1629**. However, unlike assembly **1010**, second inserter **1650** is moveable relative to handle body **1629** and may also be removable therefrom. Also, unlike assembly **1010**, sleeve **1660** is fixedly connected to an interior of handle body **1629**.

Handle **1620** is comprised of a handle body **1629** and a pull tab **1680** that can be removed from a side of handle **1620**. Tab **1680** may connect to handle **1620** via a rail (not shown) that extends from a distal end of tab **1680** which engages a slot (not shown) in handle **1620**, for example, so that tab **1680** can be pulled laterally away from handle **1620**. Pull tab **1680** forms part of a passageway that receives second inserter **1650**. First cap **1640** has an L-shape so as to make space for second cap **1670**, as shown in FIG. **20**A.

FIG. **20**A depicts assembly **1610** in a first insertion configuration. In the first insertion configuration, first and second inserters **1630**, **1650** extend through handle **1620** and sleeve **1660** so that first inserter **1630** extends more distally than second inserter **1650**. A terminal end **1662** of sleeve **1660** is positioned relative to a first insertion end **1631** of first inserter **1630** a predetermined distance so that sleeve **1660** can act as a depth stop for first inserter **1630**. Also, a second insertion end **1651** of second inserter **1650** is disposed within a passageway of sleeve **1660**. Pull tab **1680** is connected to handle **1620** and second cap **1670** of second inserter **1650** is stacked onto pull tab **1680** at a proximal location relative thereto. First cap **1640** is connected to handle **1620** at a proximal end thereof and also stacked onto second cap **1670**.

FIG. **20**B depicts assembly **1610** in a second insertion configuration. In the second insertion configuration, first inserter **1630** is removed which exposes a proximal end of second cap **1670**. In addition, pull tab **1680** is removed from handle **1620** which allows second cap **1670** to move proximally into a recess **1623**. Although a proximal surface of cap **1670** is depicted as being distal to a proximal surface of handle body **1629**, it should be understood that such surfaces can be flush in some embodiments. Positioning of second cap **1670** in recess **1623** also positions second insertion end **1651** of second inserter **1650** more distally than when assembly **1610** is in the first insertion configuration. In this regard, second insertion end **1651** is unsheathed from sleeve **1660**. Also, terminal end **1662** of sleeve **1660** is positioned a predetermined distance from second insertion end **1651** so as to act as a depth stop for second inserter **1650**.

In a method of operation of assembly **1610**, an operator impacts first inserter **1630** through tissue into underlying bone to implant an anchor mounted thereto. Once the first anchor is implanted, first cap **1640** is disconnected from handle **1620** and first inserter **1630** is removed from handle body **1629**. Tab **1680** is also removed by pulling tab **1680** laterally away from handle **1620**. Second cap **1670** is slid into handle recess **1623** which exposes second insertion end **1651** and an anchor mounted thereto. Second cap **1670** is connected to handle **1620** so as to hold second inserter **1650** in place during insertion. Operator then impacts second inserter **1650** through tissue and into bone offset from the first anchor. Impaction may be performed on a proximal surface of second cap **1670** and/or on a proximal end of handle body **1629**. Once the second anchor is implanted, assembly **1610** can be removed from the patient.

Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made and are encouraged to be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

The invention claimed is:

1. An inserter assembly for inserting anchors into bone, comprising:

a handle having a handle body;

a sleeve partially disposed within the handle body and having a passageway extending through the sleeve in a proximal-distal direction;

a first inserter partially disposed within the handle body and passageway of the sleeve, the first inserter being configured to retain a first anchor for insertion thereof into bone; and

a second inserter partially disposed within the handle body and passageway of the sleeve, the first inserter being configured to retain a second anchor for insertion thereof into bone,

wherein the inserter assembly has a first configuration in which the sleeve is connected to the first inserter so that the first inserter and sleeve are moveable together relative to the handle body, and a second configuration in which the sleeve is connected to the handle body and disconnected from the first inserter so that the first inserter is moveable relative to the sleeve.

2. The assembly of claim **1**, wherein the handle includes a first engagement feature adjacent a passageway that is defined by the handle body, and the sleeve includes a second engagement feature and is disposed within the passageway of the handle body, the first and second engagement features being configured to interface so as to hold the sleeve in releasable connection with the handle body while in the second configuration.

3. The assembly of claim **2**, wherein the first and second engagement features comprise a ball detent mechanism.

4. The assembly of claim **1**, wherein the sleeve includes a notch extending into a proximal end thereof, and the first inserter includes a pin extending outwardly therefrom, the notch and pin being correspondingly sized so as to provide an interference fit therebetween for releasably connecting the sleeve to the first inserter.

5. The assembly of claim **1**, wherein the first inserter is removable from the handle body and the second inserter is fixedly secured to the handle body.

6. The assembly of claim **5**, wherein in the first configuration, the first inserter extends further from the handle body in a proximal-distal direction than the second inserter.

7. The assembly of claim **1**, wherein the first inserter includes a cap releasably connectable to a proximal end of the handle body.

8. The assembly of claim **1**, wherein the sleeve operates as a depth stop for both the first and second inserters when in the first and second configurations, respectively.

9. The inserter of claim **1**, wherein the first and second inserters each include an insertion end configured to penetrate at least one of soft tissue and bone.

10. An inserter assembly for inserting anchors into bone, comprising:

a handle having a handle body;

a first inserter disposed within the handle body and being fixedly connected thereto, the first inserter having an insertion end configured to retain a first anchor for insertion thereof into bone; and

a second inserter slidably disposed within the handle body and having an insertion end configured to retain a second anchor for insertion thereof into bone.

11. The assembly of claim **10**, further comprising a sleeve slidably disposed within the handle body and releasably connected to the second inserter.

12. The assembly of claim **11**, wherein the sleeve extends from a distal end of the handle body and has a terminal end that is disposed more proximal than the insertion end of the first inserter and more distal than the insertion end of the second inserter when the assembly is in a first configuration, and is disposed more proximal than the insertion end of the second inserter when the assembly is in a second configuration.

13. The assembly of claim **11**, wherein the first inserter is removable from the handle body.

14. The assembly of claim **11**, wherein the sleeve is releasably connectable to the handle body.

15. The assembly of claim **14**, wherein the sleeve is releasably connected to the first inserter via a pin extending from the first inserter into a notch at a proximal end of the sleeve.

16. An inserter assembly for soft tissue repair, comprising:

an inserter handle having a handle body;

a first inserter slidably disposed within the handle body and having an insertion end extending distally from the handle body;

a first anchor defining a passageway extending therethrough and being mounted to the insertion end of the first inserter for insertion thereof into bone;

a second inserter fixedly connected to the handle body and having an insertion end extending distally from the handle body;

a second anchor defining a passageway extending therethrough and being mounted to the insertion end of the second inserter for insertion thereof into bone; and

a sleeve slidably disposed within the handle body and positioned about respective portions of the first and second inserters, the sleeve being moveable relative to the second inserter between a first and second position.

17. The assembly of claim **16**, wherein the first and second anchors are filamentary sleeves.

18. The assembly of claim **16**, wherein in the first position, a terminal end of the sleeve is located further from the handle body in a proximal-distal direction than the insertion end of the second inserter, and in the second position the terminal end of the sleeve is located closer to the handle body in the proximal-distal direction than the insertion end of the second inserter.

19. The assembly of claim **18**, wherein:

in the first position, the terminal end of the sleeve is positioned closer to the handle body in the proximal-distal direction than the insertion end of the first inserter and is positioned along the length of the first inserter relative to the insertion end of the first inserter so as to operate as a depth stop upon insertion of the first anchor into bone, and

in the second position, the terminal end of the sleeve is positioned along the length of the second inserter relative to the insertion end of the second inserter so as to operate a depth stop upon insertion of the second anchor into bone.

20. The assembly of claim **19**, wherein:

the first inserter further includes a cap connected to a proximal end thereof and is releasably connectable to a proximal end of the handle body,

the handle includes a retaining member disposed within the handle body and adjacent to the sleeve,

the sleeve includes a recess disposed along its length and configured to engage the retaining member so as to releasably connect the sleeve to the handle,

when the cap is connected to the handle body, the sleeve is in the first position, and

when the cap retaining member engages the recess of the sleeve, the sleeve is in the second position.

* * * * *